Congress was the necessity of clarifying the ambiguity in the law resulting from the *Cardiff* decision (see report of the House Committee on Interstate and Foreign Commerce, House of Representatives, Report No. 708, 83d Cong., July 6, 1953). Significantly, in this committee report, recognition was again given to the fact that the great majority of the food industry voluntarily permitted inspections to take place and that there was only a small minority group which refused to cooperate, making it necessary for the Food and Drug Administration to exercise its compulsory authority to conduct such inspections.

The committee report pointed out that the inspections were normally a matter of routine checking, primarily as to sanitary conditions, and that they were not necessarily based upon any suspicion or determination that any law had been or was being violated. Accordingly, it was concluded by the Congress that a search warrant type of procedure would be inappropriate.

The report cited is a most careful exposition of the views of the Congress upon this point. It emphasized that the bill which subsequently became the present law was not intended to authorize fishing expeditions into private papers such as financial accounts, personnel records, and payrolls. This is particularly significant in light of the amendments which are now being proposed by title II of H.R. 11581.

The committee report stated that the bill was intended to provide the Food and Drug Administration with sufficient inspection authority to protect the public by providing a means of knowing the composition of finished and unfinished materials whenever the composition of such articles is relevant to compliance with the law. It was stated that "inspection" means "to examine critically," and that the words of the proposed statute should be given a meaning with the overall purpose of protecting the public. It was stated for example, that a food and drug inspector should have authority to inquire whether a person in charge of safety controls is qualified by training and experienced but that this should furnish no basis for insistence that a person's entire life history be exposed to inspection through examination of his personnel records.

The foregoing discussion justifies the conclusion that the Food and Drug Administration was given in 1953—and still possesses—ample authority to inspect food establishments in order to carry out the responsibilities imposed upon it and there is no need at this time for expanding this authority in a manner which in 1953 the Congress did not deem desirable.

I now request the committeee's consideration of the proposed amendment.

At the heart of H.R. 11581 is section 201(a) of title II which would amend the first sentence of section 704(a) of the Federal Food, Drug, and Cosmetic Act so as to retain most of its present provisions but would add provisions which would give inspectors of the Food and Drug Administration a license to conduct what can only be called fishing expeditions into any and all matters which may directly or indirectly relate to the sanitation of the food processes at the establishment or to the wholesomeness and proper labeling of the food resulting from those processes.

The broad power thus proposed incorporates the possibility of FDA agents examining all documents and processes in order to consider those documents or processes which are relevant. Not only would FDA inspectors be permitted to enter and inspect factories, warehouses, or establishments where food, drugs, devices or cosmetics are manufactured or held but they would in addition be permitted to inspect any "consulting laboratory," its records, files, papers, processes, controls and facilities bearing on whether articles which are adulterated or misbranded within the meaning of the act or which may not be manufactured by reason of the act, have been or are being kept in violation or potential violation of the act. A "consulting laboratory" is defined as any laboratory or other establishment which, for a fee, performs or agrees to perform assays or other services, laboratory services for a food, drug, or cosmetic manufacturer if such manufacturer owns or has under his control an establishment which is subject to inspection.

In effect these provisions would give food and drug inspectors the power to conduct a roving search with undefined specific objectives, and without having to comply with even the most elementary form of search warrant procedure. Such power to investigate law violations is one jealously and wisely guarded by the common law.

All-pervasive investigatory power of this sort was one of the very things which the report of the Committee on Interstate and Foreign Commerce, referred to above, considered and refused to confer in 1953. In short, that

committee, after carefully reviewing the various types of inspection statutes which Congress enacted into law, and after considering the type of inspection necessary and desirable in the food and drug field, concluded that, since Food and Drug inspectors should primarily inspect as to sanitary conditions, and not necessarily on the basis of a prior suspicion of a law violation, that a search warrant type of procedure would be inappropriate. Now, however, the provisions of H.R. 11581 bluntly state that Food and Drug inspectors may be permitted to inspect, among other things, records, files, papers, processes, controls, and facilities bearing on potential violations of the law. Yet no effort at all is made to provide a search warrant type of procedure which is the normal and expected procedure employed by law enforcement officers.

The National Association of Margarine Manufacturers feels that the provisions of title II of H.R. 11581—designed to broaden the factory inspection powers of the Food and Drug Administration—are (a) ill-conceived, (b) are at variance with the fundamental philosophy carefully enunciated in 1953 referred to above, (c) are inconsistent with accepted principles dealing with search warrant types of procedure, and (d)—most important of all—are wholly unnecessary.

The 1958 food additives law is also highly pertinent. It changed the whole regulatory philosophy in this subject area. As this committee knows, the rationale of that law was that before an ingredient may be used in a food its safety must have been established by regulations issued by the Food and Drug Administration, thus passing in large part the burden of determining safety from the Food and Drug Administration to the industry.

Prior to 1958 it was necessary for the Food and Drug Administration to develop information to show that a food was adulterated or misbranded. Thus there is less need today than before for the broad inspection authority provisions of title II of H.R. 11581. The business community properly fears that if inspectors of the Food and Drug Administration are to be given a roving authority to make examinations of their records, files, papers, processes, etc., on the basis of mere suspecion, important trade secrets and processes may be revealed. This is particularly true when consideration is given to some of the related amendments also proposed by title II of H.R. 11581.

Thus, section 202 of the bill amends section 301(j) of the act. Section 301(j) of the act now provides that it shall be unlawful for any person to use to his own advantage or to reveal to anyone other than to the Secretary, or officers, or employees of the Department, or to the courts, any information acquired under authority of section 704 *concerning any method or processes which, as a trade secret, is entitled to protection.* But section 202 of the pending bill would strike the language above emphasized and would at the same time make it lawful to reveal any information obtained pursuant to amended section 704, not only when relative to any judicial procedure under the Federal Food, Drug, and Cosmetic Act, but also to reveal such secrets and processes as authorized by law. What does this mean? The bill does not say.

The way may be opened for inspectors to be subpenaed in purely private litigation by competitors to reveal information given to them in confidence. Certainly the Federal Rules of Civil Procedure authorize the issuance of subpenas in appropriate cases. If a trade secret became relevant in a private suit, the proposed amendments would open the way to get at these secrets through the subpena route. This is but one of the striking defects in the bill.

The business community, of which the margarine industry is a part, is keenly concerned over any disclosure of trade secrets because a secret once revealed is no longer valuable to its owner. Food and Drug inspectors are not necessarily permanent Government employees. There is nothing effectively to prevent them from using information obtained in subtle and difficult-to-detect ways once they leave their Government positions, even though they religiously lived up to their obligations under the law so long as they remained Government employees. No satisfactory remedy exists in law to repair the damage caused by the wrongful disclosure of a valuable trade secret.

The same objections as have been made regarding the involuntary disclosure of trade secrets apply with respect to other private and personal, business matters which have no legitimate relation to the performance of the statutory functions of the Food and Drug Administration. Included in this category are such matters as financial data, pricing data, sales data, personnel data, and data pertaining to research programs in all stages of development. Although information contained in each of the above categories has no relationship to whether

a given food product is misbranded, mislabeled or unwholesome, such information where improperly disclosed could wreak irreparable havoc upon business ventures and individuals associated with a food establishment. Businessmen cannot feel secure knowing that individuals outside the corporate family are possessed of the company's most vital operating data, and the public interest cannot be served where an important segment of the business community must operate under such insecure conditions.

Attention is called to fact that section 704(c) of the present law would be left unchanged by section 201 of H.R. 11581 but even this poses a problem for, as stated earlier, section 704(c) provides that, if a Food and Drug inspector takes a sample in the course of his inspection of a factory, warehouse or other establishment, he must give the person in charge a receipt describing the samples obtained. What if he obtains a sample from a consulting laboratory which the bill would authorize him to inspect. Is he to give the person in charge of the consulting laboratory a receipt?

Everyone in the food industry is mindful of the necessity for reasonable enforcement provisions, including inspection provisions. In amending the law to its present form in 1953, the Congress gave the Food and Drug Administration the utmost power which it needs to perform its task. To go beyond that is to burden unnecessarily the majority of the business community for the recalcitrance of a few. This is out of all proportion to the advantages to be gained by the Government.

The Food and Drug Administration has not, in the course of its administration of this important law, revealed any reticence to exercise fully the powers given to it in the most effective manner. Bearing in mind that the Food and Drug Administration has the power of seizure, it is almost inconceivable, with existing inspection powers, that it cannot adequately protect the food supply of the Nation. To permit it to do more is to destroy the confidence of the business community in the agency and to give it an authority out of all balance with its needs.

For the foregoing reasons the National Association of Margarine Manufacturers respectfully urges this committee to not recommend the passage of title II of H.R. 11581.

STATEMENT OF ELSIE NAOMI JONES, ATTORNEY, RE H.R. 11581

My name is Elsie Naomi Jones. I am an attorney engaged in the private practice of law in the District of Columbia with offices at 1047 31st Street NW., Washington, D.C. I am a member of the bars of the District of Columbia and the State of Tennessee. Prior to entering private practice in 1960 I was employed as an atorney in the Federal Government for 26 years with assignments in several departments. I file this statement with the committee only as an attorney who is interested in the food and drug field and who has had occasion to spend some time in study and research in such field.

Last week I attended the public hearings on H.R. 11581 and was impressed by the concern of some witnesses and committee members over placing in one man authority to determine (1) whether a new drug is efficacious before allowing it to be marketed, and (2) whether a drug already on the market presents an imminent hazard and if so, summarily remove it from the market. The proposed House bill, of course, would place this responsibility in the Secretary of the Department of Health, Education, and Welfare. As clearly brought out by the testimony and questioning, however, many drugs are admitted to be effective only as to a small percentage of users. In addition, experts do not always agree as to the degree of efficacy or the hazards posed.

In connection with the doubt expressed as to the wisdom of endowing one public official with such far-reaching authority to be exercised in areas where much conflict of expert opinion exists I would like to call to the committee's attention the existing authority of the Food and Drug Administration to achieve the removal of a food, drug, device, or cosmetic from the market by obtaining a permanent injunction in which judicial proceedings the manufacturer of the product has no right to trial by jury.

Of the three types of actions which the present Federal Food, Drug, and Cosmetic Act authorizes the FDA to institute, i.e., criminal, seizure, and injunctive, the right to trial by jury is afforded the accused in the criminal and seizure actions. However, with respect to proceedings seeking to perpetually enjoin the accused, the Supreme Court of the United States has recently denied cer-

tiorari in a permanent injunction proceeding instituted by the FDA where the failure of the court to grant a trial by jury as requested by the accused was in issue. This is the case of *United States of America* v. *Ellis Research Laboratories, Inc. et al.*[1] This proceeding involved a diagnostic aid device which had been on the market for some 30 years and sold only to doctors of medicine, chiropractors, and other persons licensed by the several States to practice in the healing arts. The record shows marked conflict in expert testimony as to the device's efficacy. Expert opinion, however, seemed unanimous that the device was harmless. The Court's ruling granting the permanent injunction has the effect of putting the manufacturer out of business and depriving diagnosticians of the device without the manufacturer having had the jury trial which he requested.

I submit that the right to trial by jury should be afforded the accused when the FDA elects to seek to perpetually enjoin as well as when it elects to proceed by the institution of a criminal action or by a seizure action. Accordingly, I respectfully suggest that an appropriate amendment is in order to H.R. 11581 so as to provide for amending section 302(*a*) of the Federal Food, Drug, and Cosmetic Act[2] by adding at the close of that section the following language: "When a permanent injunction is sought, trial shall be by the court, or, upon demand by the accused, by jury."

I thank the committee for this opportunity to file my above statement for inclusion in the record of the committee's hearings on H.R. 11581.

STATEMENT OF JACOB RECK ON BEHALF OF THE NATIONAL BEAUTY & BARBER MANUFACTURERS ASSOCIATION IN OPPOSITION TO SECTION 201 OF H.R. 11581

My name is Jacob Reck. I am counsel for the National Beauty & Barber Manufacturers Association, and herewith present its opposition to section 201 of H.R. 11581, which would expand FDA's factory inspection authority by removing restrictions and limitations in the existing law and, thus, enable FDA agents to conduct the broadest kind of search of cosmetic plants and beauty salons or barbershops in which cosmetics are held after entry into interstate commerce.

We oppose the unprecedented, unrestricted, and unlimited search authority provided for in section 201 of this bill which would subject retail and wholesale establishments where cosmetics are held after entry into interstate commerce, such as drugstores, grocery stores, beauty salons or barbershops, to an inspection of their records, files, and papers bearing on potential violations of the Federal Food, Drug, and Cosmetic Act, which means anything and everything on the premises, because the fine safety record of cosmetics during the past decade demonstrates there is no need for this broad and unreasonable inquisitorial power.

FDA's published reports of legal actions instituted against cosmetics show that in the past decade only two cosmetic products out of $15 billion worth of cosmetics sold during that period were removed from the market by FDA court action because of adulteration with a poisonous or deleterious substance. Anyone familiar with the cosmetic enforcement picture knows that a drive by FDA immediately following the enactment of the cosmetic provisions in the act of 1938 cleared the market of unsafe cosmetics more than two decades ago and that since then, for the purpose of self-preservation and to expand consumer acceptance, cosmetic firms adequately inform themselves concerning the safety of their products before putting them on the market. An increasing consumer acceptance bears out this fine record of safety.

In view of this lack of need, we contend it would be just as unreasonable at the present time to authorize FDA to inspect the formulas, complaint and personnel files of cosmetic producers and resellers as it was in July 1953 when

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[1] *United States of America* v. *Ellis Research Laboratories, Inc., et al.*, U.S. District Court, Northern Division of Illinois, Eastern Division, civil action No. 60C578, permanent injunction decree entered June 14, 1961; affirmed U.S. Court of Appeals for the Seventh Circuit, No. 13471, by opinion entered Mar. 22, 1962; certiorari denied, Supreme Court of the United States, No. 929 October term 1961, on June 11, 1962.

Should it suit the convenience of the committee I should be glad to supply the committee with names and addresses of the defendant's attorneys of record.

[2] 21 U.S.C. 332(a).

this committee, through its present chairman and ranking minority member, in the House floor debate on the compulsory factory inspection amendment, emphasized that it was the congressional intent to provide for inspection within a reasonable manner and within reasonable limits which did not include authority to inspect the formulas, profit-and-loss statements, complaint or personnel files and many other similar documents. This emphasis on the intent to limit the inspection authority was made necessary by the grave constitutional questions inherent in an unlimited, compulsory factory inspection. These difficult constitutional questions have been raised anew in the expanded inspection authority requested in section 201 of this bill. We submit that these questions require a limitation on the inspection authority now just as they did in July 1953 when your committee inserted in the factory inspection amendment a requirement that the inspection be "within reasonable limits and in a reasonable manner" for the purpose of confining the scope of inspection to "factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished materials, containers, and labeling therein." (See H. Rept. No. 708, 83d Cong., 1st sess. (1953), p. 7.)

Accordingly, we respectfully request your committee to withhold approval of section 201 of H.R. 11581 with respect to cosmetics and consulting laboratories.

STATEMENT OF JOHN S. HALL, SECRETARY OF AND IN BEHALF OF NATIONAL MANUFACTURERS OF BEVERAGE FLAVORS IN OPPOSITION TO H.R. 11581, PROPOSED AMENDMENT TO SECTION 704(a), FACTORY INSPECTION

On behalf of the National Manufacturers of Beverage Flavors, we are anxious that the views of that industry regarding House Resolution 11581 be clearly stated and understood. We appreciate the opportunity to state our position.

We agree that if a previously accepted substance or flavoring is proven to be unsafe, that prompt steps must be taken to prevent its use. However, we do not agree that the ultimate goal, protection of the consumer, is served by giving inspectors complete liberty to enter a factory with unrestricted access to "all things therein." To the contrary, our courts have consistently ruled in favor of protection of fundamental rights—which would be violated by the delegation of such strong powers for purposes of factory inspection.

We must emphasize our alarm after reading the proposed broadened authority. No personal business records, no secret formula papers would be denied access to the inspector. The proposal speaks of "all things * * * bearing on violations or potential violations * * *." To our way of thinking, this invites unlimited inspection, it invites adjudication of guilt or even presumption or suspicion of guilt by a field inspector—a man suddenly called upon to serve in the capacity of judge and jury.

Historically, the inspector's prime concern has been sanitation and general conditions of the factory premises, as related to health problems. Progress is being made and more progress will be made. The inspector's role should adapt to the desired functions. However the fundamental rights of the producer and of owners of secret formulas should not be surrendered to the inspector who, without statutory guides, can merely suspect a potential violation and use such a key to any factory and to all things therein. What policeman protecting against dire crimes is vested with this authority? What grand jury is empowered to act on such a basis? Where does this power fit in the pattern of lawful search and seizure?

To our deep concern over damage to the rights of our industry members and the value of the formulas and industrial properties they have built up, we must reiterate the concern expressed by other industries. Additional objections have been adequately expressed.

This request for unlimited power has been injected into proposed amendments dealing primarily with that section of the law covering the manufacture of drugs. Our interests are not in that field, but if any greater factory inspection authority is needed in the administration of the drug law, proposed amendments should be directed to that purpose and not to the food section of the law.

We stand willing to cooperate with the Food and Drug Administration in the mutually desired goal of protecting the consumer. But we must object to proposed legislation which, in the guise of serving that goal, destroys basic rights. If the administration can provide evidence that the present legislative authority is inadequate for a specific purpose, they should come forth so that that problem

would be fairly analyzed. Our industry will have no objection to any reasonable approach on the basis of a showing that a change is necessary. A vague expression that more power is needed is not in keeping with sound legislative growth. Thank you for permitting us to add our expressions of opposition to the proposed legislation.

STATEMENT OF JAMES B. CAREY, SECRETARY-TREASURER, INDUSTRIAL UNION DEPARTMENT, AFL–CIO, ON H.R. 11581, THE DRUG AND FACTORY INSPECTION AMENDMENTS

My name is James B. Carey. I am the secretary-treasurer of the Industrial Union Department, AFL–CIO, and president of the International Union of Electrical, Radio, and Machine Workers, AFL–CIO.

The Industrial Union Department, AFL–CIO, has come before committees of the Congress several times to testify on behalf of strong legislation to insure drug safety and efficacy, and fair prices. We have consistently taken the position that strong legislation is needed. We have done so in the interest of the 6 million industrial workers represented through the IUD and of all the American people.

It would be easy enough to say, "We told you so," in the light of the recent thalidomide tragedy. But nothing is to be gained from finger pointing and there is little that can be done for the victims of this drug "progress." It is a sad commentary upon our civilized society that we must wait until such tragedy strikes before there is corrective action.

Pressures from the drug industry prove the need for a well-armed cop to patrol the drug industry beat. Dr. Kelsey was subjected to strong and constant pressures from a company intent upon marketing its product, regardless of whether or not there was adequate proof of safety. What has happened to the Food and Drug Administration under present circumstance is worthy of congressional investigation.

Charges against FDA are outlined in the September Saturday Review by John Lear, who broke the drug industry scandals that resulted in congressional investigations. Similar charges were made in testimony of Dr. Barbara Moulton, who vainly sought to accomplish what Dr. Kelsey heroically achieved. Dr. Moulton charged in testimony that the Food and Drug Administration had become "in many areas a service bureau" for the drug industry.

Legislation cannot of itself guarantee that such circumstances will not arise again, that there will be no new scandals like that involving Dr. Henry A. Welch, who headed the Antibiotics Division of FDA until it was revealed that he had used that position for personal gain. But legislation giving the Secretary of Health, Education, and Welfare adequate police power can change the entire orientation of our Food and Drug Agency.

The people must be guarded against any "buyer beware" philosophy in drug merchandising. They have little choice in the matter except to believe the label, or take what the doctor prescribed. In no other industry is there such urgent need for strong legislation.

The thalidomide tragedy is only the latest in a long series of drug mishaps due to lack of adequate safeguards. The case of MER–29 was nearly as serious. Here, too, the chief concern of the drug industry was to get the compound to market regardless of proof of safety.

FDA Deputy Commissioner John L. Harvey now agrees that the drug should never have gone on the market. It seems probable that had there been adequate safety requirements the drug would have been withheld.

In this case too, the FDA doctor who cleared the drug was subjected to strong industry pressures And even if these had not been applied, the law is such that MER–29 would have soon been on the market. Current law permits applicants to market new drugs if they have not been disapproved by the FDA within 60 days.

MER–29 resulted in cataracts, skin problems and other injurious side effects. Yet, even after the side effects were reported, the drug continued to be prescribed. Over 300,000 patients had used the drug before it was withdrawn. Even while efforts were being made to force withdrawal, an ad in the American Medical Association Journal claimed that there were "few toxic or side effects reported."

The age of miracle medicines has made it more important than ever that we proceed with care. These medicines have made wonderful cures possible, but

they have also brought us to new thresholds of body chemistry. Unless there are adequate precautions, the cure may prove as dangerous as the illness.

Rheumatic arthritis is a merciless affliction. It was no wonder that when decadron was introduced in 1956, thousands turned to it for relief. Side effects ranging from simple rounding of the face to severe mental disorders were soon evident. Yet, 2 years later, advertisements continued to proclaim: "No worrisome side effects contributable to decadron have occurred as yet."

The drug industry has failed to learn from experience. Voluntary restraint has proved woefully inadequate. The drive has been for the quick (profit) kill with the quick pill. It is a miracle that there have been no worse tragedies.

H.R. 11581 goes a long way toward correcting the situation now prevalent. It does not, in our view, go as far as it should. However, we urge quick passage of the measure as a decisive step forward on the road to sanity in drug manufacture and marketing. The bill will protect patients, doctors, and even the drug industry against itself. It will provide means to combat the manufacture of drugs under unclean or unsafe conditions. In itself, this will be beneficial to the responsible drug company because it will help to eliminate the drug bootlegger who is now able to prevent plant inspection, and who now does not even have the legal obligation to register as a drug manufacturer.

H.R. 11581 would require drug manufacturers to register with the HEW Secretary. Only those who have something to hide need fear this provision. And certainly, those with something to hide have no place in the drug industry.

In our view, the drug registration provision does not go far enough. While we are in favor of passage of the measure as written, we shall continue to push for a law requiring that drug manufacturers be licensed by the Federal Government. The ability to grant, withdraw, or withhold license is essential for adequate policing of the industry and for the enforcement of proper standards of safety and efficacy.

The bill would require each applicant seeking approval to market a drug to establish and maintain records of its effectiveness and its side effects and make these records available to the Government. This will be of significant help in keeping useless and—more importanly—harmful drugs off the market. We are in full agreement with the requirement.

The provisions covering factory inspection are long overdue. Such inspection will insure cleanliness in plant operation, protection from adulteration, and the proper branding of products. It will give Federal inspectors access to papers, records, files, processes, controls, and facilities. This will make inspection meaningful.

The IUD is not impressed with arguments that factory inspection will result in invasion of industrial privacy, or the pirating of business secrets. In the first place, the public health and safety is more important than business secrets. In the second place, there is adequate protection within H.R. 11581. The law proclaims that information obtained by inspectors is confidential. Certainly, trade secrets will be as confidential as they are now, in view of advanced chemical analysis and electronic snooping.

The law, as presently written, permits FDA only very limited rights in checking qualifications of drug personnel. These rights will be broadened under the proposed law. This will be a step forward since the safety of the consumer is intimately tied up with the qualifications of key personnel.

We are especially pleased with that section of the law which gives the HEW Secretary the right to order a drug off the market if he finds that clinical, or other experience, or tests show the new compound unsafe or of no medical value. Too often, the consumer must wait for tragedy before a drug is withdrawn under present circumstances. The consumer will be significantly safer if this provision becomes law.

Testimony before this committee and in the other body of the Congress has attested to the exorbitant prices of drugs, and to the fantastic profits of the industry. Certainly, under such circumstances, the consumer has the right to expect efficacy and relief from the medicines he is offered. This, in far too many cases, has not eventuated. Drugs often are not injurious but neither are they effective. The scandal of RDX and of safflower oil capsules illustrates the point. Power to remove useless drugs from the market will be an effective tool in calming down exaggerated claims for drug efficacy.

No drug should be permitted on the market if it represents a hazard to the public at large. H.R. 11581 would remedy this situation. The IUD is of the view that the bill's section, which authorizes the HEW Secretary to withdraw such drugs, is indispensable.

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The argument has been raised that the law will place the HEW Secretary in the position of a czar. Nothing could be further from the truth. The law requires that withdrawal orders shall be accompanied by detailed findings. Court review is also provided. The honest manufacturer who seeks to serve the sick will have nothing to fear.

The batch testing requirement in the case of antibiotic represents consumer protection of a vital kind. It will insure better quality control, as well as added safety. It is difficult to understand industry objections to this provision. In view of promotional and pricing policies of the industry, its sudden concern about added costs is hardly impressive.

We are gratified to note that H.R. 11581 requires the truth in advertising claims for prescription drugs, together with a listing of side effects, active ingredients by usual name and contraindications of the drugs. Exaggerated claims made in drug advertising have been shameful. They have cruelly raised the hopes of the sick, the aged, and the infirm. It is time that the truth should be made an elementary requirement of this advertising. It is inhumane to permit this industry to take advantage of people who grasp at almost any straw in the hope of cure or relief from pain. Here, too, there is an area of confusion and massive misinformation. The cost of patent medicines reaches into the billions. Certainly, as RDX proved, there is a need for truth in advertising in this area, equal to that in prescription drugs.

The general tightening up in the area of barbiturates and other habit-forming stimulant drugs provided in the bill should have the approval of the drug industry itself. The expanded use of such stimulants has exacted a toll reflected in prison records, delinquency, and brutal crimes. The public welfare demands the bill's regulation, and the IUD gives its full endorsement.

H.R. 11581 would extend the time in which the Government could examine a new drug application. This should aid materially in relieving unwarranted pressures on FDA doctors. With a maximum of 180 days for study and investigation, instead of the present 60 days, the probability of decisions in the interests of public safety will be greater.

We strongly favor the granting of power to the HEW Secretary, permitting him to keep a new drug from the market until it is proven safe and effective. This right cannot be exercised arbitrarily, as some have alleged. The right of review and recourse to the courts is clearly available.

The Industrial Union Department hails as a step forward, the provision in H.R. 11581 that gives the HEW Secretary the right to standardize drug names. This will help to eliminate much confusion and will facilitate prescription by generic name. This is an essential step toward fairer drug prices.

The requirement that the standard or generic name shall appear on the drug label, and that the quantity of each ingredient—if there is more than one—shall also be stated, is another welcome step in this direction. The need for consumer protection in this area is greater today than ever. The wonder drugs of our day grow increasingly expensive, and the most expensive way of obtaining them is by brand name. It is our hope that these requirements will influence pricing policy in the drug industry so that the consumer will finally get a break.

We are disappointed by one major lack in H.R. 11581, which we feel is essential if drug prices are to be held down. Badly needed is modification of the patent laws as applied to drugs.

It is our belief that no patent should be granted on any new drug unless there is a substantive change and improvement. As things stand, a slight alteration of the formula is sufficient for a new patent. Drug research, as a result, has stressed changes sufficient to enable rival firms to come up with duplicate products. Research has been geared to promotion, and the stress is on the new, rather than the better.

In the decade ending with 1959, some 3,500 new products hit the ethical drug market and another 1,100 new dosages of existing products were also marketed. Of the new products, 88 percent were combinations of drugs already on the market or duplications of existing products. Such practices have added to the confusion and costs in the drug field.

Patent monopoly in the area of new discovery has permitted the drug industry to charge what the traffic will bear. Truly competitive pricing policies will not be established until the patent laws are changed to permit true competition in the manufacture of the same product. Exclusive patents should be granted for not more than 3 years, after which provision should be made to require the licensing on fair terms, of all who want to enter the field.

The Industrial Union Department, AFL-CIO, recognizes that H.R. 11581 represents a long step forward. While it is of the view that patent reform is fundamental in drug policy, it takes the position that its exclusion should not be reason to hold up the bill before this committee.

The IUD will continue to work for improved drug legislation in line with the Nation's needs. It will continue to press for patent reform. Such reform is essential if the price gouging made possible by the ills and the suffering of millions of us is to be ended.

At the present time, patients have no knowledge that they are sometimes used as guinea pigs when new drugs are introduced. Patients should have the right to reject such drugs and doctors should be required to inform patients that they are being treated with trial drugs. We urge the inclusion of such a provision in the measure before you.

The IUD applauds the work of this committee in the field of drug legislation and commends its chairman for introducing this bill. It is our hope that it will soon be reported to the House floor. New drug legislation that will protect the public can be a major accomplishment of the second session of this Congress. We are gratified at the unanimous vote for similar legislation that came in the Senate last week.

In view of what has been revealed in more than 2½ years of drug hearings, it is difficult to understand the position taken by some industry spokesmen. We are, in fact, appalled by the views of some, who last week came before your committee.

We refer the committee to the NAM News of August 24. A front page story there is headed, "Drug Industry Fears Effect of Emotional Congress Action." The NAM, indeed, and the drug industry, show little respect for the judgment of the Congress.

The pharmaceutical industry takes the position that H.R. 11581 represents over regulation. The representative of the Pharmaceutical Manufacturers Association testified that "careful" study is required and that there should be no "drastic changes" in the law. He termed the efficacy requirement of H.R. 11581 "nebulous." It would seem that the manufacturers want to maintain "flexibility" on this matter.

Let us look at the "flexibility" that now exists. FDA Deputy Director Kenneth L. Milstead, in a speech to the Yonkers Academy of Medicine a few months ago, was reported as saying that FDA would crack down on doctors who—

> Arrange for tailored studies to permit a drug promoter to advertise that a product has been clinically tested, although only a few uncontrolled observations on a few patients have been made.
>
> Rent themselves out as "consultants" to drug firms and then agree to rig drug test procedures so that the results will be as predetermined.
>
> Use as treatment-for-pay-medicine drugs labeled "for investigational use" without submitting proper clinical reports necessary for the evaluation of the drug's benefits or harmful effects.

How many more thalidomide tragedies does the drug industry need?

It is interesting to note that the drug industry would now try to point to the thalidomide tragedy as proof that new legislation is not required because the drug wasn't actually marketed. Yet, thalidomide would have been marketed had it not been for a conscientious FDA employee upon whom the industry brought heavy pressure to release the drug. It is also strange that the lack of law in other nations should be used to justify inadequate law here. Yet, this has been done in testimony before this committee.

The big question is whether the "quick kill with the quick pill" outlook shall go unchallenged. It is a question of whether profits or public safety shall come first. We take the position that reasonable profits coming from service to the Nation are the kind America needs, while profits resulting from denial of the public welfare are harmful.

The New York Times of August 26 carried a front-page story headed, "Scientists Fear New Laws May Curb Drug Research." A reading of the article shows that those most concerned are representatives of the industry.

The fear is that tight restrictions on clinical testing will result from new legislation. Yet, we find no such restrictions in H.R. 11581. True, the Senate legislation would give the HEW Secretary the right to require animal tests, but there is nothing in the proposed legislation that would halt clinical testing. We feel that the industry and others are building a strawman.

It has been proposed that a qualified advisory committee of scientists be named to help draft sensible proposals to insure safeguards for the people, especially in the area of clinical testing. This may help to supply an answer and is worthy of the consideration of FDA. We find no reason, however, to believe that either the proposed legislation or newly announced HEW regulations will result in the hampering of clinical testing. We cannot believe that the HEW Secretary would act against clinical testing in any specific case, unless there were good reason to doubt the safety for human use of the drug in question.

We take this occasion to remind the Congress that the best of laws can become meaningless without adequate funds for enforcement. Funds granted up to now have been inadequate for the FDA to carry out its functions as it should. FDA has a tremendous responsibility in an increasingly vital area. This responsibility must not be abused nor should there be any excuse for neglect.

STATEMENT FOR CONSUMERS RESEARCH, INC., SUBMITTED BY F. J. SCHLINK, PRESIDENT AND TECHNICAL DIRECTOR, CONCERNING H.R. 11581, SECTION 202

The proposed amendment to section 301(j) of the Food, Drug, and Cosmetic Act concerning confidentiality of information is apparently intended to protect from disclosure and from improper use such private information as might be obtained from inspections of premises and examinations of records found in such premises.

We can understand the need or some such provision in conjunction with the extended powers of inspection provided by section 201 of H.R. 11581. However, section 202 goes far beyond any needs which would be created by enactment of section 201. The proposed new rule about confidentiality would not only protect from disclosure such information as might be obtained from inspections, but the amendment as set forth in section 202 would also throw an unwarranted and highly improper statutory blanket of secrecy over a wide range of other matters which ought to be open to public scrutiny.

For example (and this may be the most important single example), section 202 would make it a matter of law that the entire contents of food-additive petitions be held in confidence. These would include petitioners' reports about tests as to the safety of such additives. We believe it is beyond question that the reports of such investigations should be freely available to the public, and especially that they should be available for examination and study by the scientific community. It is through the wide dissemination of scientific reports that the asserted findings are tested against the expert knowledge and opinions of all those other scientists who are informed in a special field of knowledge and who should have the opportunity to read and consider published reports, freely available to all who are interested.

Section 202 would require the withholding from the public of much other vital information. The list is too long and varied to give here; it would include just about every piece of information required to be submitted by manufacturers under many important sections of the Food, Drug, and Cosmetic Act. Under some circumstances, it would perhaps become possible for a manufacturer to seal the lips of the Food and Drug Administration as to a grave danger to the public welfare simply by including certain information in a report or petition to that agency.

The provisions of the Food, Drug, and Cosmetic Act are in many respects a patchwork of amendments upon amendments. Each of several chapters of the act now has more or less appropriate requirements as to confidentiality of information. These separate rules were established by the Congress with careful consideration as to their effects. The change proposed by section 202 of H.R. 11581 would have a widespread disruptive effect on established rules in a way which we do not believe the Congress could possibly intend.

We recommend that section 202 of H.R. 11581 be entirely rewritten. It should provide for appropriate confidentiality of such information as is obtained through factory inspections and is properly to be withheld from competitors, and should be severely limited to that purpose. We believe that section 301(j) of the act need not be amended at all in this connection, but that the necessary provisions should be included as a subsection of section 704, which deals with factory inspections.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington D.C., June 22, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR CHAIRMAN: In testifying before your committee on June 22, 1962, Mr. Thomas Austern, representing the National Canners Association, commented on testimony presented on June 19 by Secretary Abraham Ribicoff.

The portion of Secretary Ribicoff's testimony to which Mr. Austern referred was:

"Evidence obtained during inspections over a number of years have shown that some of the tomatoes of the King's Creek Canning Co. operating five canneries on Maryland's Eastern Shore were unfit for food. The firm has consistently refused to furnish full information about interstate shipments. Many shipments are made by the manufacturer's own trucks. In 1959 gross insantiary conditions were encountered during inspection of the plants. We found fly eggs and maggots in the canned tomatoes. We were able to locate and seize only three shipments which probably represented less than 5 percent of the firm's output.

"Thus the refusal of this canner to furnish complete shipping records resulted in the marketing and consumer consumption of large quantities of filthy, maggoty canned tomatoes."

Mr. Austern indicated that one of the lots of filthy tomatoes referred to by the Secretary was released to a charitable institution for consumption following Federal seizure Mr. Austern indicated that this was reported in our Food Notice of Judgement No. 27381.

Each of the three lots of filthy tomatoes referred to in the Secretary's testimony was seized in 1959, condemned and destroyed. The Food Notice of Judgement No. 27381, to which Mr. Austern referred, has to do with a seizure made 2 years later in 1961; it was not seized because of the presence of filth but rather because the tomatoes did not meet the requirements of the applicable food standard by reason of excessive liquid, and it was, as Mr. Austern indicated, delivered to a charitable institution.

May I ask that the record be amended by inclusion of a copy of this letter? I am sending a copy of this letter to Mr. Austern.

Sincerely yours,

JOHN L. HARVEY, *Deputy Commissioner.*

NATIONAL CANNERS ASSOCIATION,
Washington, D.C., June 28, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR CHAIRMAN: Deputy Commissioner John L Harvey of the Federal Food and Drug Administration has forwarded to me a copy of his letter of June 22, 1962, in which he comments on a portion of my testimony on that day on behalf of the National Canners Association before your committee.

In his letter, the Deputy Commissioner states that I "indicated that one of the lots of filthy tomatoes referred to by the Secretary was released to a charitable institution for consumption following Federal seizure." Mr. Harvey also quotes what he believes to be the part of Secretary Ribicoff's testimony to which I was referring in my testimony.

An examination of the official transcript of my testimony will readily make it clear that there was no "indication" on my part that I was referring to the 1959 shipments

On the contrary, I specifically said "Now, there was a third seizure of 600 cases in June 1961 That is FDA Notice 27-381" (transcript, p. 184). Both the date and the citation were given

In addition my references to the Secretary's testimony were not limited to the portions quoted in Mr Harvey's letter.

The Secretary (transcript, pp 36–37) made it clear that he was not talking about the year 1959 alone in describing the operations of the named processor. He referred to "evidence obtained during inspections over a number of years."

He talked about a consistent refusal to furnish information about interstate shipments. He then continued by talking about "case after case" in which foods that went "distributively all over the United States," to "thousands and thousands of retail outlets," were "adulterated and unsafe goods."

His apparent point was that the departmental proposal for authority to search through all of the files was supported by this example of a processor's refusal to furnish shipping records of the movement by his own trucks of what was called "adulterated and unsafe goods" (transcript, p. 37). It would be difficult indeed to read all of the Secretary's observations without concluding that the entire packing operation of the particular canner was implicated by his statements.

As the transcript of my testimony makes perfectly clear, I did not refer to the Secretary's animadversions on this packer in pointing to the existing FDA authority to get shipping records and its other powers presently authorized on the facts reported by the Secretary (transcript, pp. 177–179).

Instead, I did so later in discussing the possibility of what I called "casual publicity" being damaging to a particular company. As I put it, the committee had "heard that man's pack talked about in most derogatory terms" (transcript p. 184).

My reference to the later 1961 seizure was intended to rebut the clear implication of Secretary Ribicoff's testimony that everything the named canner packed was unfit. In fact, our search revealed only three notices involving the packer whose name had been so unhappily used in the hearings.

It occurred to us that the best refutation of the Secretary's implication concerning this canner's entire pack was that another lot of this packer's tomatoes had been subjected to intensive examination by the FDA and that no evidence was found that the packer's tomatoes were unfit for food. This June 1961 seizure was based solely on the ground that under the applicable regulations the goods were not properly labeled under section 403(h)(1). The notice of judgment specified that after default the tomatoes were delivered to charitable institutions.

It is our view that the charge and disposition in this seizure make it clear that the 1959 charges were in all likelihood confined to a particular period in that packing season, and that since that time this packer's product has been free of the alleged conditions so unhappily described by the Secretary.

We are confident, however, that the committee will appreciate that the specific reference to a named canner by the Secretary in his testimony, which is somewhat unusual in itself, was offered to support the FDA's contention that the proposed amendments to section 704, authorizing their inspectors to have access to food plant files and records, are necessary to enable the FDA, to carry out its enforcement responsibilities under the act.

Reference to an earlier part of the transcript, dealing not with casual unfortunate publicity, but with the specific existing powers of the FDA under the provisions of the present act (transcript, pp 178–180) will indicate that I offered four specific reasons why the particular example offered would on the asserted facts in no way support the proposed amendments in title II.

If the "evidence obtained during inspections over a number of years" was as reported, the emergency permit control provisions of section 404 of the law might have been brought into play. The provisions of section 302 providing for injunctions, which have been utilized by the FDA in the past, were also applicable. And if the evidence was as cogent as suggested, a criminal prosecution under sections 301(a), 303, and 402(a)(4) was also available.

But more important, I suggested that if the processor was using his own trucks, section 703 of the law would require the production of shipping records. That section now authorizes the FDA to "have access to and to copy all records showing the movement in interstate commerce of any food." It applies to all carriers engaged in interstate commerce, which in our view includes those delivering in their own trucks. But a specific written request is required, and the congressional prohibition against the use of these records in a criminal prosecution becomes applicable.

Accordingly, in this earlier portion of my testimony, an effort was made to demonstrate that the report of prevailing operating conditions yielding unfit food, coupled with the refusal to furnish shipping records, could abundantly have been dealt with under the existing act, and hence offered no support for the requested authorization for a sweeping and recurrent examination of all records and files.

I am confident that on a full reading, the transcript, both of the Secretary's and of my testimony, will speak for itself. In order that no misunderstanding may exist, I would appreciate your including in the record a copy of this letter along with that of Mr. Harvey.

Very truly yours,

H. THOMAS AUSTERN, *Counsel.*

NATIONAL ASSOCIATION OF FOOD CHAINS,
Washington, D.C., August 28, 1962.

Mr. W. E. WILLIAMSON,
Clerk, Committee on Interstate and Foreign Commerce,
U.S. House of Representatives, Washington, D.C.

DEAR MR. WILLIAMSON: This statement is submitted by the National Association of Food Chains, Inc., in opposition to section 201(a) of H.R. 11581, the "Drug and Factory Inspection Amendments of 1962." The association is composed of approximately 250 corporate food chains, ranging in size from as small as 2 store operations to organizations distributing through more than 2,000 stores.

Section 201(a) of H.R. 11581 would greatly expand the present inspection provisions of section 704 of the Food, Drug, and Cosmetic Act to authorize carte blanche inspection of "all things" in any establishment, including food stores, which bears on any violation of the act. The practical effect of this section of the bill is to make it impossible for anyone to refuse Government inspection of anything, including all business records.

NAFC recognizes that Government inspection is necessary in some instances to uncover violations of Federal law. This inspection authority should, however, contain some limitations to protect the legitimate interests of law-abiding businesses. Section 201(a) ignores this important principle. It eliminates any protection against unwarranted Government fishing expeditions, it invades the business privacy of food store operators, and it raises serious questions as to whether it permits unconstitutional search and seizure.

Moreover, the costs to a company's operations of such a widespread and detailed inspection may well be considerable. These costs, in turn, must be passed on to the consumer.

No attempt has been made in these hearings to demonstrate why such broad inspection authority would further the remedial purposes of the law. Certainly, no such need is based upon any alleged violations by NAFC members.

The Food, Drug, and Cosmetic Act can impose criminal penalties upon unknowing violators. To include food store operators within the coverage of this bill is therefore not only unjustified but is also a dangerous extension of governmental inspection authority.

Respectfully submitted.

CLARENCE G. ADAMY,
Executive Vice President, National Association of Food Chains.

VIENNA, VA., *August 21, 1962.*

DEAR SIR: During your committees deliberations on the drug mess I thought perhaps the enclosed might be of interest to you. It is not directly related but since some of the ingredients mentioned are also drugs there is a direct tie-in. I am generally unalterably opposed to Federal meddling in controls but recognize some are absolutely essential. This is one area that needs bolstering to combat the commercialism involved.

Do your children or grandchildren consume quantities of ice cream?

Sincerely,

N. D. EPPLY.

[From Prevention, August 1962]

ADDITIVES BY THE HALF-GALLON—IF YOU EVER THOUGHT ICE CREAM WHOLESOME FOOD, YOU WILL BE STARTLED AT THE REVELATIONS ABOUT WHAT EACH DELICIOUS SPOONFUL REALLY CONTAINS

The kids this year have over 200 flavors of ice cream to pick from though chances are that they'll choose one of the old standbys—chocolate, vanilla, or strawberry. For the more adventurous, there are rhubarb, mango, and coconut caramel to try.

The mango is described as "intensely lemon-colored," so it should meet with great success. Color is very important in the ice cream business, and an ice cream flavor whose color is "intense" is the most likely to get its fair share of a market which has every American licking or spooning over 1.. pounds of ice cream per year.

Ice cream manufacturers have also discovered that ice cream which holds its expected texture longer sells better. The customer enjoys eating it more and the salesman in the store finds it nicer to work with.

In the course of his education the ice cream manufacturer soon becomes aware that to make a full-flavored ice cream takes a lot of flavoring. A lot of berries, chocolate, bananas, peaches, etc., cost a lot of money. So the manufacturer is usually graduated into a new approach—synthetic flavorings.

It is easy to see how the pattern of modern ice cream has developed. It is the story of the development of most modern food industries, whose aim is to make more cheaper, with no regard for food value, and little for safety. This is what has caused the gravest danger to us, in our food supply. Prevention finds this heedless profiteering cause for great alarm.

NO PROTECTION IN THE LAW

It took until 1958 for the United States Government to do anything at all about regulating by law the standards under which ice cream is produced. What went on in the industry before that was unspeakable. Now there is some control, but still one cannot help being astounded at the many dangerous additives that continue to be used in ice cream. Furthermore, Federal law does not control many aspects of manufacture in products which are sold exclusively within a single State—as most ice creams are. The States themselves are inconsistent in what they require in an ice cream. By and large, the ice cream industry has a fairly free hand in what it sells to the consumer as a final product.

All of this information became quite apparent as we read through a recently published book, "Ice Cream and Related Products," by J. H. Frandsen and W. S. Arbuckle. The book is intended as a basic handbook on the manufacture and selling of ice cream. As such, it gives a pretty full picture of what one is getting when one takes a half-gallon of ice cream home from the supermarket. Of course, Prevention's objections to commercially sold ice cream start with the most basic ingredient, the milk. Milk is no better for the body when it appears creamy and frozen than when it is poured from a bottle. The milks and creams in ice cream contain the same excessive talluess factor, the same butterfat, the same objectionable antibiotics and the same allergenic properties that Prevention has warned against for years.

But milk is only one of the drawbacks in ice cream. Sugar, for another, presents an even greater hazard to the body, and sugar constitutes up to 20 percent of what is sold to you as ice cream. Sugar is the one item in our diets that robs us most freely of valuable B vitamins, and sets our blood sugar to doing roller-coaster climbs and plunges. If there is any nutritive merit in the milk products in ice cream, the sugar quickly snuffs out any advantage. As "Ice Cream and Related Products" evaluates sugar's part in ice cream, "The main function of sugar is to increase the acceptance of the product, not only by making it sweeter, but more especially by enhancing the pleasing creamy flavor and the desired delicate true fruit flavors."

We doubt that parents who disallow their children candy and do allow them to eat ice cream are aware that every dish of ice cream a child eats contains two or three tablespoons of sugar. And if your family goes through the popular half-gallon package every week, as many families do, they're adding an extra pint of pure sugar to their already unimpressive diet.

CHEMICALS AND MORE CHEMICALS

Have you noticed that the ice cream in late years is notably free of ice crystals and has a smooth creaminess about it? That's no accident. It's the result of stabilizers, and emulsifiers. The stabilizers used to be of gelatin animal sources such as the skins and bones of calves and pork, or of vegetable sources: agar-agar, certain types of seaweed, etc. Today there has been a general switch to a cheaper synthetic chemical, sodium carboxymethylcellulose (CMC) is the basic stabilizer being used by the ice cream industry of the present day.

Emulsifiers are another of the strange things that have happened since making ice cream moved from the back porch to the factory. These are described as valuable for "the improved whipping quality of the mix, the production of a drier ice cream with a smoother body and texture having superior drawing qualities at the freezer, and more exact control which can be maintained in the various manufacturing processes." Natural emulsifiers such as eggs, milk proteins, fat lecithin, etc., have given way to the monoglycerides and diglycerides and to compounds known collectively as the poly compounds. The glycerides are artificial fats, which Prevention condemns for several reasons, not the least of which is their propensity as with all processed fats, to open the way to cancer and raise the natural cholesterol level of the blood.

The polyglycerides, of which polyoxyethylene monostearate is a commonly encountered example, have been used in breads, salad dressings, and ice cream. Federal law prohibited their use in these products, because, as one former Food and Drug Commissioner put it, they would make "good paint removers." Some are used for this purpose, as well as for antifreeze in cars and coolants in airplane engines. An elixir sold in the 1940's, and guaranteed to cure kidney disease, strep throat, or gonorrhea, contained diethyl glycol. After 105 men and women had died as the result of taking the elixir it was recalled from the market. Is diethyl glycol in your ice cream? The Federal law which outlaws the use of polyglycerides covers interstate commerce, but many ice cream manufacturers have designed their products for local consumption only. Unless the specific State has a law which prohibits polyglycols, chances are that local manufacturers will use it.

However, an even more offensive area of additives in ice cream is that of artificial flavoring and coloring. There are Federal laws against the use of artificial colorings or flavorings in ice cream. How well do you think they are observed on the State level?

SOME TASTY POISONS

Sales figures bear out the fact that vanilla is the most popular ice cream flavor of all. "Ice cream and Related Products" gives a run-down of the compounds now used to give ice cream that popular vanilla taste. You can be old fashioned—and extravagant—and use real vanilla beans. (Even these don't sound too appetizing when we learn that the extractions are prepared from finely cut vanilla beans in a solution of not less than 35 percent alcohol.) You can get vanilla concentrates, vanilla pastes, blends that contain true vanilla extracts mixed with synthetic, and preparations which "contain no vanilla bean extractives."

As the flavor desired gets more specialized, so does the method of acquiring it. Commercial ice creams almost never use the natural substance to attain the bulk of the flavor intended. In the book, "Food Flavorings," by Merory, we came across a chapter entitled "Imitation Flavors." Many of these formulae are the ones used to flavor the ice cream we are offered. Here is the recipe for banana flavorings:

	Grams
Imitation violet-formula MF 140	7.2
Benzyl propionate	22.0
Ethyl caproate	24.0
Heliotropin	24.0
Vanillin	24.0
Coumarin substitute	24.0
Linalaol	40.0
Amyl valerate	60.0
Amyl butyrate	120.0
Acetaldehyde	120.0
Amyl acetate	534.8

We investigated these ingredients in the Merck Index and came up with some surprising and disconcerting background on some of those that were listed. Heliotropin was found to be a drug, which if used in large amounts, will cause depression of the central nervous system. Amyl valerate is a substance that has been used as a sedative for hysteria. Amyl acetate is used to perfume shoe polish and in the manufacture of artificial silk, leather and in dyeing and finishing textiles. It is also known to cause headache, fatigue, and irritation of mucus membranes upon continuous exposure. Acetaldehyde is used, among other things, in the manufacture of plastics. It irritates the mucus membranes, and

has a general narcotic action. Large doses may cause death through respiratory paralysis. Its toxicity symptoms are similar to those of chronic paralysis.

This formula for banana flavoring was chosen at random from a listing of dozens of similar ones offering common flavors such as butterscotch, tutti-frutti, and blueberry in Mr. Merory's book. Banana ice cream is just one of many whose flavoring ingredients would give one reason to be concerned.

Other flavorings containing specific undesirable ingredients are: cherry-piperonal, a substance used to kill lice; aldehyde C-17, an inflammable liquid used in aniline dyes, plastics and synthetic rubber; pineapple-ethyl acetate, a chemical used for cleaning textiles, whose vapors may be irritating to the mucus membranes, and may damage the heart, the kidneys and the liver; nut flavor—butyraldehyde, used in rubber cement, rubber accelerators and synthetic resins; strawberry-benzyl acetate, a substance that can cause vomiting and diarrhea; black walnut-ammonium valerate, a medical sedative.

COLORS PRETTY BUT DEADLY

In coloring techniques, the additives men have had a field day, and ice cream manufacturers are right there waiting to make use of any new development. A technical book entitled "Synthetic Food Adjuncts" by Morris B. Jacobs, Ph.D., carried an interesting page on color association as it is understood by most food manufacturers, especially those who make confections such as ice cream. In the listings we saw such recommendations as "blackberry-dark, bluish-red; nut-walnut to golden brown; pistachio-bright green; strawberry-bright, bluish pink."

The author thoughfully lists a grouping of various shades of the primary colors, with the formulae for the different dyes to be mixed to achieve them.

BLACKBERRY

Dark

Amaranth: Caution: consult latest Government regulations before using this dye in foods, drugs, and cosmetics.
Indigotine: Dark blue dye.
Glycerol: Used as solvent, humestant, emollient, sweetener, in cosmetics, liquid soaps, confectionery, blacking, printing and copying inks, also in the manufacture of nitroglycerol. Medical use: vehicle for antitussines.

Bluish-red

Ponceau 3r: Caution: consult latest Government regulations before using this dye in foods, drugs, and cosmetics.
Tartrazine: Caution: consult latest Government regulations, etc.
Indigotine: Dark blue dye.
Glycerol: See above.

NUT

Walnut

Amaranth: Caution, see above.
Tartrazine: Caution, see above.
Orange I: Orange dye.
Ponceau 3R: Caution, see above.
Indigotine: Blue dye.
Glycerol: See above.
Fast green: Dyeing silk, wool, jute, leather.
Medical use: Antiseptic for bacterial and mycotic infections.

GOLDEN BROWN

Amaranth: Caution, see above.
Orange I: Orange dye.
Tartrazine: Caution, see above.
Erythrosine: Brown color; caution, consult latest government regulations before using in food, dyes, and cosmetics.
Ponceau 3R: Caution, see above.
Brilliant blue: Dye for cotton and silks. Medical use: has been used as an antiseptic.

PISTACHIO

Bright green: Tartrazine. Caution, see above.
Brilliant blue: Dye, see above.
Light green: SF yellowish dye.

STRAWBERRY

Bright—amaranth: Caution, see above.
Tartrazine: Caution, see above.
Bluish pink: Indigotine—dye.
Glycerol: See above.
Erythrosine: Caution, see above.

As you can readily see, what one ordinarily thinks of as ice cream—milk, sugar (even that is often a synthetic sweetener), eggs and fruit, or real vanilla or powdered real chocolate—is not what we buy at the store nowadays. Probably an ice cream manufacturer with ideals of purity and honesty of product could not exist in his competitive industry.

And this conglomeration of chemical filth is what they have the nerve to offer to the public as a pure and nutritious food, especially good for children! We have even seen its use advocated as a breakfast food, atop dry cereal!

Ice cream is as jazzed-up a product as one can buy. Every trick in the book has been employed to make its appearance attractive, if deadly, and its manufacture as cheap as irresponsible methods permit. It is difficult to believe that intelligent people would permit their children to eat it, even occasionally, if they understood the chemical garbage it contains.

Show this article to your friends, for the sake of their little ones if for no other reason. And please, as you value your health don't ever succumb yourself to those pretty colors and sweet flavors achieved with deadly chemicals.

THE AMERICAN PUBLIC HEALTH ASSOCIATION, INC.,
Washington, D.C., August 21, 1962.

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, New House Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: The American Public Health Association has, for several years, been concerned with the problems resulting from the manufacture and sale of an increasing number of drugs. In the opinion of the APHA, serious defects have become apparent during recent years relative to the clinical investigation, distribution, promotion and advertising of hundreds of new drugs which are marketed in the United States annually. These inadequacies are evidenced by the fact that since 1957 at least 19 drugs have had to be recalled or withdrawn. The following is a list of 15 of these drugs and manufacturers, and the reason for recall or withdrawal follows:

Manufacturer	Drug	Reason for recall or withdrawal
Lederle Laboratory	Lederle liver injection with folic acid.	Mislabeled—contained epinephrine injection.
Sandoz, Inc	Landostene	Agranulocytosis.
Blair Laboratories	Kerid	Swelling and soreness of the ear.
G. F. Harvey	Cerulav	Do.
Purdue Frederick Co	Cerumenex	Do.
Eaton Laboratories	Furadantin oral suspension	Subpotent.
Pfizer Laboratories	Syngesterone aqueous suspension.	Potency variations.
Hoffman LaRoche	Marsalid	Liver damage.
McNeil Laboratories	Flexin	Hepatitis.
White Laboratories	Entoquel	Severe atropine-like reaction in infants.
Upjohn	H F C albamycin	Labeling error.
Eaton Laboratories	Altafur	Dangerous side effects.
Upjohn	Monase	Agranulocytosis.
E R Squibb & Sons	Pentids "400"	Mixed in error with pentids sulfa syrup.
Wm S. Merrell Co	MER/29	Caused cataracts, baldness, etc.

The severity of this situation has recently been brought to the attention of all through the tragic experience in thousands of pregnant women abroad following their use of thalidomide. In this instance one of the most serious defects in the problem of drug control was clearly indicated—that is the lack of adequate preliminary research before clinical investigation is permitted. Investigation of new drugs does not regularly include careful research of the drug on pregnant animals. Also, clinical investigators are not always fully apprised of possible and dangerous side effects. This, it seems to us, was demonstrated in the use of thalidomide resulting in congenital malformations in thousands of newborn babies.

In the light of these problems relating to the multiplicity of new drugs and the tragic experience with thalidomide, the executive board of the APHA on August 14, 1962, approved the attached statement and has requested that it be made available to your committee in order that you may know the position of our association relative to this matter. Additional information which may be of assistance to your committee will be provided at your request.

Respectfully yours,

NOBLE J. SWEARINGEN,
Director, Washington Office.

STATEMENT OF THE EXECUTIVE BOARD, AMERICAN PUBLIC HEALTH ASSOCIATION, AUGUST 14, 1962

The American Public Health Association expresses deep concern occasioned by reports of the occurrence of large numbers of congenital anomalies in several countries from the prescription for pregnant women of an insufficiently tested drug marketed under a number of different proprietary names.

We strongly commend the work of Dr. Kelsey, a member of the staff of the FDA who prevented the release of the drug for sale in the United States. At the same time in order further to diminish the possibility of the promotion and sale of harmful drugs in the United States, the American Public Health Association—

(1) Reaffirms the importance of its resolution on drugs adopted in 1960 urging on welfare, health, and other public agencies limitation of public expenditures for drugs to those prescribed by nonproprietary generic names included in United States Pharmacopoeia or National Formulary (accepted dental remedies) or if not included approved by a qualified formulary committee.

(2) Emphasizes the importance of strengthening the power of the Food and Drug Administration to require satisfactory evidence of safety before any drug is released for general use, both by legislation and by increased appropriations to permit expansion of qualified professional and technical staff.

(3) Requests that the FDA require that generic names be printed on labels and in advertising in equal prominence with proprietary names.

(4) Recommends that by legislation or regulation release of drugs for trial in human patients be conducted according to protocols which meet the standards to be established by the FDA in consultation with the PHS and which conforms to principles of ethics in clinical research established by the AMA.

(5) Particularly calls attention to the risk of congenital anomalies resulting from use of inadequately tested drugs and urges that drugs which may be used during pregnancy be subjected to suitable tests as to teratogenic effect prior to their approval by FDA.

(6) Recommends that the appropriate authorities of the Federal Government establish restrictions upon the import into the United States of drugs not approved for sale in the United States except for clinical trials under protocols to be established by the FDA.

(7) Calls upon the pharmaceutical industry to hasten the implementation of these measures of protection for the public by initiating voluntary action to these ends pending the development of new regulations and the enactment of needed legislation by the Federal Government.

THE UNITED STATES PHARMACOPOEIA,
New York, N.Y., August 24, 1962.

Re H.R. 11581, antibiotics certification.

HON. OREN HARRIS,
Chairman, Committee on Interstate Commerce,
House of Representatives, Washington, D.C.

DEAR SIR: This will convey the information on antibiotics certification that I promised to provide in response to a request made by Congressman Roberts during my appearance as a witness on August 22.

Of the hundreds of substances discovered in the past 20 years that may be classed as antibiotics by virtue of the fact that they are produced by living organisms, relatively few have been introduced for use as drugs. These latter constitute only slightly more than a dozen different basic molecular structures. I have compiled a list of them, together with certain information that bears on the need for their being subject to batch certification.

During my appearance on the stand, Congressman Moss read from an address recently delivered by Mr. John L. Harvey, Deputy Commissioner of FDA, in support of the legislation now before Congress. With respect to batch-by-batch certification, Mr. Harvey stated that certification of all antibiotics is needed because (*a*) "antibiotics are the first choice in treating life-threatening infectious conditions"; (*b*) most antibiotics are produced by processes that are complex and yield "undesirable byproducts"; and (*c*) "the potency of antibiotics must be determined by biological assay procedures, the interpretation of which requires unusual competence."

I regret that, not having seen a copy of the address earlier, I was not in a position to comment on it adequately during the questioning period. Hence I wish now to offer some remarks.

With respect to point (*a*), there is no disputing that antibiotics are the first choice in treating many infectious conditions but this blanket statement requires considerable qualification. In the view of the outstanding physicians who serve on the U.S.P. Committee of Revision, it is best to use one of the newer sulfa drugs in many cases in preference to antibiotics. However, infectious diseases make up only part of the medical emergencies that physicians face daily so that the role of antibiotics in medicine is not so different that, as a class, they should be given different status under the law.

The statement (item (*b*)) that antibiotics are produced by complex processes which sometimes lead to undesirable products also does not distinguish this group from other drugs for which the same thing may be said. One of our most important groups of drugs are those which produce relaxation of muscles so as to facilitate the work of the surgeon. The first of these, tubocurarine chloride, is the poisonous ingredient of what is popularly known as "arrow poison" and is obtained from crude materials collected by South American tribesmen. The best methods of extracting tubocurarine yield a product that contains other substances having undesirable activity. With respect to synthetic muscle relaxants, the chemical manufacturing process is such as to require great care in eliminating harmful byproducts. Hence an argument based on complexity or undesirable byproducts is scarcely moving in putting the antibiotics in a class by themselves as requiring special FDA handling.

With respect to item (*c*), it is simply not true that the potency of antibiotics must be determined by biological assay, because chemical assays are used for many of them, as is indicated in the enclosed table. The FDA itself uses these chemical assays. Furthermore, this again does not place the antibiotics in a separate class because there are many drugs which are not subject to certification that can be tested only by biological assay. I need mention only digitalis, the indispensable heart drug; posterior pituitary, the drug used in childbirth; or heparin, which is used in the emergency of acute heart attacks to prevent further clotting of the blood in the coronary artery. Other less important drugs also require biological standardization. Insulin-containing products also require biological standardization, but these of course are subject to a type of batch certification that works less hardship on producers and does not require duplicate

testing on the part of the Government. Indeed, if the certification of antibiotics were put on the same basis as that of insulin, the present proposals would be less objectionable.

The ultimate destination of the fees paid the Government for the antibiotics program was the subject of a regrettable misunderstanding between me and Congressman Moss. The point I wanted to make is simply that once a Government agency has built up a testing unit for which it charges fees, it is unrealistic to expect that unit to recommend its own abolishment. If we cannot depend upon the Congress to look carefully into the continued need for such services, I am sure that citizens will have a right to feel that they are not being adequately represented.

With respect to the statement that antibiotics certification costs only one-twentieth of a cent per dose, the fact should be brought out that this is an overall average for the industry, and is made up of widely disparate figures. For the large manufacturer who submits a large batch of antibiotics, the testing fee is not much larger than that charged for a small batch submitted by a small manufacturer so that the latter's cost per dose is much larger. This will tend to drive the small producers of antibiotics completely out of business. A trend in this direction is already indicated in the pharmaceutical business for other reasons as shown by a recent survey completed for and published by the Pharmaceutical Manufacturers Association. This shows that during the past 20 years, 544 new basic drugs were introduced. One-third of these were developed by 5 firms alone and three-fourths of them were developed by only 19 firms. With respect to the role played by the antibiotics in this picture and the trend to concentration in the industry, the record shows that nearly one-fifth of the total of 544 drugs were antibiotics or closely related drugs also used to treat infections.

There is a further aspect of the true and full cost of the FDA certification program that bears examination. This is the immense cost in technical manpower which, as estimated by the Comptroller General in his 1960 report to Congress, amounted to 126 man-years in 1959. An estimate given by another witness this week put it at 170 man-years for 1961. Skilled technicians are too scarce and FDA needs them elsewhere too much for it to continue devoting such a huge effort to the duplication of testing already done.

It is of interest to note that the above-cited Comptroller General report states, on page 10, in respect to the fees paid for the FDA testing of antibiotics, insulin, and colors:

"In the fiscal year 1960, about $13.5 million was obligated for the enforcement program and $1.3 million was obligated for the certification program. The certification program was financed by fees received from users of the service."

For the reasons cited in my statement and above, we feel that your committee will do a great service to the public welfare by limiting batch certification to the antibiotics that really need it.

In order to expedite delivery of this letter I am sending it only in triplicate. Additional copies will be sent next week.

I thank you again for the courtesy of your attention last Wednesday.

Sincerely yours,

LLOYD C. MILLER, Ph. D.,
Director of Revision.

Antibiotics in current use, with estimate of need for FDA batch certification on basis of state of purity, and the kind of assay required

[Legend U.S.P., Official in United States Pharmacopeia; N.F., Official in National Formulary]

Antibiotic	Present official status	Number of therapeutically useful variants [1]	General state of purity and stability	Biologic assay required	Suggested need for batch certification
Amphotericin			Good	Yes	Probable.
Bacitracin [2]	U.S.P.		do	Yes	Do.
Chloramphenicol [2]	U.S.P.	2	Excellent	No	None.
Colistimethate			Fair	Yes	Definite.
Erythromycin	U.S.P.	6	Excellent	No	None.
Fumagillin			Fair	Yes	Probable
Gramicidin	N.F.		Excellent	Yes	None.
Griseofulvin			Good	Yes	Probable.
Kanamycin	U.S.P.		Excellent	Yes	None
Neomycin	U.S.P.		Good	Yes	Do.
Novobiocin	U.S.P.		do	Yes	Do.
Nystatin	U.S.P.		do	Yes	Do.
Oleandomycin		2	do	Yes	Probable
Penicillin [2]	U.S.P.	13	Excellent	No	None.
Polymyxin	U.S.P.		Good	Yes	Probable.
Ristocetin			Excellent	Yes	Do.
Streptomycin [2]	U.S.P.	2	do	Yes	None
Tetracycline [2]	U.S.P.	5	do	No	Do.
Tyrothricin	N.F.		Good	Yes	Do.
Vancomycin			do	Yes	Probable.
Viomycin			Fair	Yes	Do.

[1] If more than 1 form is useful.
[2] FDA certification now required for most batches.

NATIONAL FRUIT & SYRUP MANUFACTURERS ASSOCIATION, INC.,
New York, N.Y., July 18, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The purpose of this communication is to reaffirm the position which our members have taken with respect to H.R. 11581 opposing, without reservation, those provisions of the said bill with regard to factory inspection that would enlarge the authority of Food and Drug inspectors so as to allow the invasion of the files and records, including such confidential material as formulas and processes of a manufacturer.

Our members rightly feel that such enlargement of authority would not in any way prevent adulterated or mislabeled food from reaching the public but would expose the manufacturers' private and confidential formulas to the danger of falling into the wrong, unauthorized hands.

We further feel that the present laws covering factory inspection adequately protect the consuming public by insuring shipments of wholesome foods prepared under sanitary conditions.

For the foregoing reasons, we again place ourselves on record as being definitely opposed to the legislation in question on which the public hearings which have been held before your committee are being continued.

While we do not ask for leave to appear before the committee personally, at the continued hearings, we respectfully urge that our opposition to this bill appear on the record.

Respectfully yours,

ROBERT M. RUBENSTEIN,
Executive Director and Counsel.

HILLS BROS. COFFEE, INC.,
San Francisco, Calif., June 14, 1962.

Subject: H.R. 11581.

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR HARRIS: As a part of the U.S. food industry, we are deeply concerned over the ultimate effect of this bill presently under consideration.

The food industry fully subscribes to the principle of consumer protection as provided for under the basic laws with respect to the Food and Drug Administration and particularly the compulsory factory inspection amendment of 1953, which confined this power to matters of sanitation and specifically prohibited burdensome investigations not pertinent to the basic principles involved.

We take particular exception to "Title II: Clarification of and Strengthening of Factory Inspection Authority," which should be deleted in its entirety insofar as it applies to the food industry.

Some basic reasons for opposition

(1) Unlimited inspection authority is contrary to basic American principles.

(a) Since the public has not suffered under present law, it is not necessary to sacrifice principle for unproven gain.

(2) Research and development will be retarded, since trade secrets and processes would be subject to disclosure by Government inspectors whether deliberate or inadvertent.

(a) To counter this, manufacturers would tend to switch their research and development activities to foreign countries at the expense of American industry and labor.

(3) The cost of these types of inspections (Government and industry expense) will ultimately be passed along in the form of taxes and cost of goods to consumers.

(4) Foreign-produced goods are not subject to the same regulations and consequently enjoy a competitive advantage at a time when American industry is being hard pressed.

We believe that under present law the American consumer is adequately protected on foods processed in the United States. Furthermore, the consumer will gain the benefits of improved products at lower cost through research and development and fostering of competitive home industry.

Since the U.S. food industry is at a competitive disadvantage and the consumer is not protected in the same manner or to the same degree with foreign food products, we feel that a real service could be rendered by reviewing that particular phase of consumer protection.

Yours very truly,

REUBIN W. HILLS III, *President.*

THE R. T. FRENCH CO.,
Rochester, N.Y., June 13, 1962.

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR REPRESENTATIVE HARRIS: We understand your committee will begin hearings on H.R. 11581 (drug and factory inspection amendments to the Federal Food, Drug, and Cosmetic Act) within a very short time. Although we are not able to send a corporate officer to these hearings, we nevertheless feel our position on this amendment might be of interest to you.

The relationship between reputable grocery manufacturers and the Food and Drug Administration has been marked for a long time by a cordial and mutual respect. This is due to a number of reasons, among them the recognition that the activities of the FDA benefit the industry as well as consumers. There has also been close contact between FDA and the industry at numerous conferences and through the independent Food Law Institute. We are at a total loss to see how the enforcement of the Food and Drug Act will in any way be benefited by H.R. 11581.

We have FDA inspectors on our premises at various times. We know of no instance when there was any difference of opinion over what they could or should look at. They go about their business most capably, assisted by members of our staff whenever necessary.

The unlimited powers of inspection into personnel records, complaint files, secret formulas, etc., appear to use to be an unnecessary and conceivably hostile invasion of privacy by the Federal Government. This great authority could be abused by inexperienced inspectors or by ones with a grudge against a particular grocery manufacturer. Moreover, it would adversely affect the beneficial climate in which the grocery manufacturing industry and the FDA operate.

Most manufacturers have the impression, warranted or not, that H.R. 11581 was written more for its political salability as a supposed consumer aid than for any practical purpose of improving the efficiency of FDA enforcement or food product quality.

Sincerely,

C. R. YOUNG, *Secretary.*

LIBBY, MCNEILL & LIBBY,
Chicago, Ill., July 10, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Libby, McNeill & Libby has been engaged in the processing of canned foods for almost 100 years and now also operates facilities in the Northwest, Florida, and on the east coast for the freezing of fruits and vegetables. It is one of the world's largest suppliers of a diversified line of canned and frozen foods, with processing facilities located throughout the mainland and in Hawaii, and with extensive plant facilities in foreign countries. Its domestic and foreign-produced products are marketed throughout the free world.

This company has over its long history consistently supported the 1906 Food and Drug Act, the enactment of the Food, Drug, and Cosmetic Act in 1938, and the several amendments to that act, through the National Canners Association, representing substantially all of the Nation's producers of canned fruits, vegetables, meats, specialties, and seafoods.

We wish to voice our vigorous objections to the enactment of title II of H.R. 11581 and strongly endorse the detailed statement of opposition submitted by the National Canners Association on behalf of its membership on June 21, 1962, and the oral presentation made by the association's general counsel, Mr. H. Thomas Austern. The NCA statement sets out in great detail the many substantial reasons for our opposition to this unwarranted demand for increased authority on the part of the Food and Drug Administration over canners and freezers. There is no country in the world supporting a higher standard of esthetic values than the United States, and nowhere is there such a plentiful supply of wholesome, quality food products than is prepared in this country. It is our firm conviction that the increased inspection authority sought under this bill is wholly unnecessary and no reasonable explanation has been advanced to support the suggested amendment of section 704 of the present Food, Drug, and Cosmetic Act.

The unprecedented authority granted under this proposed bill to search the property and records of the canners and freezers raises, in our view, serious and substantial doubts as to its constitutionality.

Furthermore, we believe it is certain to follow that broadened authority will be accompanied subsequently by demands for more inspectors and increased budgets for FDA—all at a time when we have long since reached the point where the vesting of additional controls in Washington which are patently unnecessary exceeds both good judgment and sound practice and the people's ability to meet the increasing tax burden. The hearings before the committee, we are confident, will not produce testimony in support of any demonstrated need for such further control and, in the absence of concrete evidence to the contrary, the request for broadened inspection authority should be defeated.

The Food and Drug Administration, as has been pointed out for the record, already possesses ample powers of inspection and investigation which are in every way adequate for the protection of the public interest. The present language in section 704 providing for mandatory factory inspection was carefully considered and adopted only after extended congressional deliberation. The intervening years of long experience with that section has served to amply confirm the decision made at that time.

The request for broadened inspection authority over foods will neither serve the purposes and objectives of the Food, Drug, and Cosmetic Act, nor make any constructive contribution to the progress the food industry has shown under the present act. We stanchly support the statement submitted by the National Canners Association and ask that our views likewise be made a part of the record.

Sincerely,

ROBERT L. GIBSON, Jr.

88589—62——42

KALAMAZOO SPICE EXTRACTION CO.,
Kalamazoo, Mich., July 5, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: This letter concerns provisions in H.R. 11581 now pending before your committee concerning permission granted to inspectors of the Food and Drug Administration to examine all records, papers, etc., of food manufacturers. In particular, my letter is addressed to chapter 7, section 704(a), entitled "Factory Inspection." This is on page 15 of the Ramseyer print.

My company is actively engaged in the processing of spices and other condiments for use in the food industry in the United States. We have supported insofar as we could the food additive and color additive amendments, and were one of the first firms to have a food additive amendment issued. We are in sympathy with the objectives of the food and drug regulations, which are now in existence, as well as with the objectives of H.R. 11581.

We feel, however, that before the broad powers of examining records, papers, research work, etc., are granted to inspectors of the Food and Drug Administration, an overwhelming case should be made for the unsatisfactory operation of the present provisions for factory inspection. Needless to say, violations of the law are now taking place which would be prevented if these powers were granted to food and drug inspectors, but I think it better to allow these violations to continue through difficulty with enforcement of the present act, provided there is not serious danger to the public health, than to increase the authority of the Federal Government to invade hitherto private areas of personal and business life.

It is my opinion, based on experience with the controls and objectives of major food manufacturers in this country, that products are not incorporated into foods which are injurious to the public health on a significant scale, and never knowingly by responsible food manufacturers. I do not believe that the factory inspection provisions would significantly impair the operation of most food manufacturers, but would make it more difficult for some of the marginal operators to do what they are now doing. The danger of revealing processes and secret formulas can well be overemphasized, as it has been my experience that little is very secret in food industry. Particularly, secrets are usually lost within a period of a few years.

The important issue, therefore, in our opinion, is whether or not further incursion by the Federal Government into what has here been considered private affairs of individuals or corporations should be encouraged. It is my understanding that it is possible for Congress to subpena any papers of any corporation if they so desire, in connection with an investigation, and it is my belief that similar seizure of papers could be effected by agents of the Government under court warrant. Although this would be too cumbersome a procedure for day-to-day regulatory control, it nevertheless provides an avenue for investigation by your committee as to whether or not the inspection powers are necessary and in the public interest.

It is always easy to attempt to control an alleged evil by enacting a restrictive law, and such a law may indeed eliminate some of the evil. In our free society, we must decide how far we should restrict the freedoms of individuals to prevent the unethical person from taking advantage of others. I should prefer to have us err on the side of too much freedom, rather than too much restriction, and this is why I believe that modifications of section 704 should not be made unless an overwhelming case has been prepared indicating the absolute necessity.

I should appreciate your incorporating these remarks in the record of the committee if possible.

Very truly yours,

PAUL H. TODD, JR.,
President.

ASSOCIATION OF NATIONAL ADVERTISERS, INC.,
OFFICE OF THE PRESIDENT,
New York, N.Y., August 28, 1962.

Congressman OREN HARRIS,
U.S. House of Representatives,
Washington, D.C.

DEAR CHAIRMAN HARRIS: I am writing concerning H.R. 11581 and specifically to express the serious reservations this association has about section 131 of the bill which involves advertising.

ANA does not have a primary interest in the prescription drug, or any other vertical industry as such. Its concern is to preserve and advance sound, effective, and wholesome employment of national advertising processes for all American business.

ANA is strongly opposed to the principle inherent in section 131 of H.R. 11581 of automatically requiring by legislative or agency mandate the incorporation of any lengthy statement into the advertising of a given product.

Advertisements are, by their nature, unavoidably limited in the space or time available for communicating their messages. The smaller the advertiser, and the less money he can devote to advertising, the more curtailed will be the physical boundaries within which he must operate.

There simply is not the time or space in print or broadcast media for an advertiser to set forth extensive dissertations concerning his product or service.

To require that he do so is, in effect, to forbid him from advertising at all. The smaller the company, and the less its ability to invest in long commercials or large space advertisements, the more effectively would it be barred, by regulatory requirements for affirmative disclosures, from using advertising in its competitive efforts.

The law in its present state already protects the public against an advertiser's failure to disclose those additional matters which need to be stated in order to prevent deception from arising out of his claim and no further legislation is needed for that purpose.

In this connection our attorney reminds me of the following section of Wheeler-Lea Act: "* * * in determining whether any advertisement (of a food, drug, device, or cosmetic) is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisements, or under such conditions as are customary or usual" (Wheeler-Lea Act of March 21, 1938, 52 Stat. 111, 15 U.S.C. 55(a)(1)).

These illustrative cases, brought under present law, prohibited deception created by the advertisers' failures to disclose important matters in connection with their advertised claims (*Ward Laboratories, Inc.* v. *F.T.C.*, 276 F. 2d 952 (2 Cir. 1960)), (*Wybrant System Products Corp.* v. *F.T.C.*, 266 F. 2d 571 (2 Cir. 1959)), (*L. Heller & Son, Inc.* v. *F.T.C.*, 191 F. 2d 954 (7 Cir. 1951)), *American Medicinal Products* v. *F.T.C.*, 136 F. 2d 426 (9 Cir. 1943)).

Section 131 would go further, however. It would impose upon an advertiser, even one who might wish to publish no more than the brand name of his product, the obligation to set forth in his advertisement virtually a textbook chaper describing all the conditions for which it will (and will not) be efficacious, its side effects and its contraindications including, we suppose ("full and accurate"), all exceptional, variant and qualifying circumstances and influencing factors.

Administered as written, this would, as a practical matter, make impossible all small space prescription drug advertisements, and almost all large ones.

Extended to nonprescription drugs, or to virtually any other products, arbitrarily compelled recital of detailed product specifications within the four corners of a print advertisement, or in the 10, 20, 30 or (at most) 60 seconds of a broadcast commercial, would fatally restrict the use of the advertising process as such.

Advertisements are physically not equipped to serve as product manuals. Legislative or administrative efforts to impose that function upon advertising could not be complied with and, hence, ultimately could only force its abandonment.

For these reasons the ANA is deeply disturbed over the underlying concept which, so far as it knows, appears for serious legislative consideration for the first time in section 131.

If advertising space and time can be preserved for the communication of brief messages, designed to engage the interest or stimulate the recollection of potential customers in the advertiser's product, and if detailed specifications, as desired by the purchaser, are available through labeling, product brochures, or other more suitable media, the public will be adequately protected, and advertising's indispensable stimulant effect upon American commerce, and its competitive aid to the users of the small print advertisements and spot commercials in entering and remaining in the national marketplace, will not be put into a straitjacket.

Sincerely yours,

PETER W. ALLPORT.

MANUFACTURING CHEMISTS' ASSOCIATION, INC.,
Washington, D.C., August 29, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The Manufacturing Chemists' Association, Inc., a trade association with a membership representing more than 90 percent of the Nation's chemical productivity, is concerned with the sweeping new factory inspection provisons of H.R. 11581 now pending before your committee. These provisions are found in sections 201 and 202 of the bill which would extend the existing factory inspection authority in the Food, Drug, and Cosmetic Act to include records and all other things in affected factories bearing on violations or potential violations of the act.

Our analysis of these provisions has been conducted solely in terms of their impact on our member companies who manufacture food and food additives. As to their impact on manufacturers of drugs, we defer to the views expressed by the Pharmaceutical Manufacturers Association and others more intimately concerned with that aspect of the matter. Thus, our interest involves the new factory inspection proposals as they related to food or, more particularly, to food additives.

Our concern centers on two aspects of the proposed additional inspection authority:

(*a*) The threat to confidentiality of trade secrets, research, pricing and sales data, and personnel records of individual employees.

(*b*) The constitutionality of such authorization of unlimited inspection for purpose of uncovering evidence of violations or "potential violations," in possible derogation of rights against unreasonable searches and seizures guaranteed by the fourth amendment.

In the absence of a clear showing that the Food and Drug Administration must be given such sweeping authority to protect the public health, the wisdom of granting such broad inspection powers should be open to serious doubt. We believe that review of the testimony in these hearings and, in fact, of all events since the 1953 amendments to the Food, Drug, and Cosmetic Act, would demonstrate no such need.

In view of the passage by the Senate of S. 1552 restricting these new inspection powers, with appropriate limitations, to manufacturers of prescription drugs, it would seem appropriate to modify sections 201 and 202 of H.R. 11581 in a similar pattern. Certainly, the imposition of the proposed unlimited inspection authority without adequate demonstration of need, at least insofar as manufacturers of food additives are concerned, seems unwise and unjustified.

On behalf of the Manufacturing Chemists' Association, I, therefore, strongly urge that food and food additives be excluded from the factory inspection provisions of H.R. 11581 and would appreciate your placing this letter in the record of the hearings so that our views can be given most careful consideration by all members of your committee and of the Congress.

Sincerely,

J. E. HULL.

THE WINIFRED MASTERSON BURKE RELIEF FOUNDATION,
THE BURKE FOUNDATION REHABILITATION CENTER,
White Plains, N.Y., August 28, 1962.

HON. OREN HARRIS,
House of Representatives,
Washington, D.C.

DEAR MR. HARRIS: I have just sent you a wire regarding impending legislation aimed at restricting clinical and scientific appraisal of drugs in an effort to reduce incidental hazards. Although the aim of such legislation may be laudable, there is great concern on my part, as well as that of fellow scientists, that such restrictions may unduly hamper medical progress and have the ultimate effect of impeding the attack of medicine on many diseases. The restrictions imposed by the present legislation, had they been in effect 20 years ago, would have reduced or made impossible the availability of antibiotics and cortisone-like substances.

Accordingly, it is requested that these matters be considered in action upon this bill (S. 1552).

Very truly yours,

ANTHONY A. ALBANESE.

NOVILLE ESSENTIAL OIL CO., INC.,
North Bergen, N.J., August 28, 1962.

Congressman OREN HARRIS,
Chairman, House Interstate and Foreign Commerce Committee
House Office Building, Washington, D.C.

DEAR MR. HARRIS: Please permit us to go on record that we emphatically support and agree with the statement made by Mr. Frank F. Dittrich, president of the Essential Oil Association of U.S.A., before the House Committee on Interstate and Foreign Commerce, relating to H.R. 11581, which is now being reviewed by your committee.

It is our candid opinion that there is no historical or valid reason to support the need for factory inspection of perfume oils used in products for external application only.

The lifeblood of our business is the formulas for the making of fragrances developed by us continuously, and having their roots in traditions going back for centuries We have not a single case on record, having been in business for over 20 years, where the perfume oil which we supplied to our many customers, even remotely could be blamed for harm to the human body. On the other hand, being exposed to a possible violation of secrecy through factory inspection, could jeopardize the very basis of our business to which we have dedicated our whole life, and on which depend innumerable numbers of people for their livelihood.

We feel this is the essence of our objection to H.R. 11581, and the more elaborate exposition by Mr. Dittrich before your committee, should surely convince you of the justification of our stand.

Respectfully submitted.

A. G. NICKSTADT, *President.*

BLAIRSTOWN, N.J., *August 28, 1962.*

Mr. W. E. WILLIAMSON,
Committee on Interstate and Foreign Commerce,
U.S. House of Representatives, Washington, D.C.

MY DEAR MR. WILLIAMSON: The Food and Drug Administration's grasp for added authority to inspect papers, files, books, and records in food plant offices as contained in H.R. 11581 should be rejected.

The requested expansion of so-called factory inspection authority to permit FDA inspectors to rummage through business records in food plants has nothing to do with current problems in the drug field. Efforts are being made to ride the unhappy results of the thalidomide episode to secure enactment of unnecessary and unwise legislation having to do with papers, books, and records in dairy and other food establishments.

Title II of H.R. 11581 which has to do with factory inspection should be disapproved by the House Committee on Interstate and Foreign Commerce because it is unnecessary and unwise.

Authority to inspect business papers and records of food establishments is not necessary because the food supplies of the United States are the purest, safest, and most nutritious in the world.

Added authority is unnecessary because under existing law food and drug inspectors:

(1) May inspect the food plant and all machinery and equipment bearing on sanitation;

(2) May inspect all ingredients and finished products, manufactured in the plant;

(3) May take samples of raw materials and finished products for analytical purposes;

(4) May inspect all containers and packaging material used;

(5) May inspect all of the labels and labeling material;

(6) May demand shipping records from carriers or from persons holding products in question in civil proceedings and may use time-honored court processes in criminal prosecutions.

Added authority to the Food and Drug Administration to inspect papers, files, books, and records is unwise. Congress itself, in enacting compulsory factory inspection in 1953 stopped at factory inspection, and the House committee explicitly did not authorize business records inspection.

Added authority to inspect papers and files in food establishments is unwise because:

(1) Based upon "potential" violations it constitutes a "fishing license."

(2) Under the language of the legislation private, company formulations (trade secrets) are not protected.

(3) It will fail of its purpose because fly-by-night operators who would engage in willful adulteration would not be expected to keep records.

(4) It is believed that the provisions of title II cannot be reconciled with the prohibitions against unreasonable searches contained in the fourth amendment to the Constitution.

(5) And finally, even though title II was held unexpectedly to be constitutional, the legislation sanctions an erosion of the rights of citizens which have been enjoyed since the founding of the Republic.

Respectfully submitted.

T. O. HOFMAN.

ALBERT EINSTEIN COLLEGE OF MEDICINE,
YESHIVA UNIVERSITY,
DEPARTMENT OF PHARMACOLOGY,
New York, N.Y., August 28, 1962.

HON. OREN HARRIS,
House of Representatives,
Washington, D.C.

MY DEAR MR. HARRIS: I have deliberated a long time before addressing myself to your committee, as the lateness of this communication testifies. I am most confident of the wisdom of decisions reached by a carefully conducted investigation of a congressional committee. However, I am apprehensive of amendments to proposed legislation which may arise from emotional reactions that have little basis in fact. I would therefore like to outline to you some of my thoughts that relate to procedures for the control of the introduction of new drugs.

Before proceeding, let me state my qualifications for the opinions I am about to express. I have been an academic pharmacologist for 30 years. During that time I have been on the faculty of Yale and Columbia and presently am chairman of the department of pharmacology at the Albert Einstein College of Medicine. During the war years I was a major in the Army, United States and served as chief of the pharmacology section of the Medical Division of the Chemical Warfare Service. I was a member of the investigating team that introduced the use of the highly toxic chemical warfare agents, the nitrogen mustards, for the treatment of human cancer. I was a member of the first pharmacology and experimental therapeutics study section of the U.S. Public Health Service and subsequently served two additional terms, one as chairman. I am coauthor of a widely used textbook of pharmacology and am a past president of the American Society for Pharmacology and Experimental Therapeutics. I am presently a member of the Pharmacology Training Committee of the U.S. Public Health Service and a member of the executive committee

of the Division of Medical Sciences of the National Research Council. During the past decade I have also had close contacts with pharmaceutical industry as a consultant.

Lastly, before proceeding, may I say that although I respectfully request that my opinions be incorporated in the record of the hearings of your committee on H.R. 11581, they are being addressed solely to you in your official capacity. Indeed, I do not ask to appear to testify for there is little that I can add to my following remarks.

One of the greatest achievements of modern medicine has been the progressive increase in life expectancy. This has often been confused with a change in life span. Nothing could be further from the truth. The potential span of life is little or no different than in biblical times. It requires millenniums to change the genetic characteristics which inevitably result in death.

However, life expectancy has increased tremendously and more and more of our population can look forward to the enjoyment of their full life span. Many factors have contributed. One of the most significant relates to improved prenatal and early postnatal care. Advances in nutrition have also been of primary importance. The science of immunology has made outstanding contributions to public health. In recent years, however, the major influence in the increase in life expectancy has resulted from drug therapy. The greatest advances have occurred in the field of infectious disease but it is becoming more and more obvious that metabolic diseases, degenerative diseases, mental diseases, and even malignant diseases may soon be treated with equal success.

This achievement is a matter of record. It has been accomplished by the combined efforts of basic and applied research in the environment of academic and clinical medicine and pharmaceutical industry. According to the testimony of some, we are rashly decimating our population by the hasty introduction into therapy of new drugs that have been inadequately studied in laboratory animals. Nothing could be further from the truth and actuarial statistics belie it.

During the course of any major medical advance there is a small minority that may take advantage. But this does not apply to the ethical pharmaceutical laboratories that have made such important contributions to current progress. I could cite many examples from my personal experience where the cautious and conservative attitude of pharmaceutical industry has delayed the clinical trial of drugs by months to years. These responsible members of pharmaceutical industry would welcome reasonable legislation to protect them from the onus created by those who are less dedicated. However, legislation which imposes restrictions on an area of medical research which has made such a major contribution to public health cannot be constructive if hastily considered under circumstances when emotion conquers reason.

The problems relating to the clinical trial of drugs are legion and cannot be adequately met by blanket legislation. Permit me to cite just a few examples. Preliminary investigations in a few selected patients by experienced clinical pharmacologists represent an early stage of drug development. Most drugs fail to pass these early tests, occasionally because of unexpected untoward effects, but more commonly because of lack of efficacy in man. To impose severe restrictions on the early testing of candidate therapeutic agents by experienced investigators in a research environment could halt progress in the field of drug therapy. Of course, precauctions must be taken and careful animal testing must be performed before these initial clinical trials, but they need not and indeed cannot be as elaborate as those necessary when more extensive clinical testing is contemplated. Finally, when a drug is to be given to thousands of patients, but still on a trail basis, the precautions must be just as great as those exercised before the release of a drug for general use. No ethical pharmaceutical company would take exception to such restrictions since they are already self-imposed.

Another problem which must be carefully considered before blanket restrictions are placed on the clinical testing of drugs relates to the seriousness of the disease which is being treated. A drug to be tested in the treatment of cancer may have serious toxic effects in animals and yet be acceptable for clinical trial in man. On the other hand, no serious toxicity can be tolerated in drugs that are employed for minor symptomatic therapy.

It is obvious, therefore, that legislation directed toward the control of clinical trials of drugs in man must be considered most carefully if the brilliant progress that has been made in pharmacotherapy over the past several decades and which has contributed so much to the health and welfare of the Nation is not to be jeopardized. The new regulations relating to the clinical trial of new drugs proposed by the Secretary of Health, Education, and Welfare are well conceived

and offer protection to the public. Sixty days are provided to consider opinions expressed by academicians, physicians, pharmaceutical industry and other interested persons. Surely if regulations are so carefully considered, legislation should be no less hasty and should result from recommendations of a carefully selected scientific study committee reporting to a congressional committee. There is no crisis in the offing that could result in any more serious consequences than legislation that is designed to promote public health but would have the opposite effect because of hasty judgment.

Finally, I am concerned that for many years in the future the objectivity of the dedicated personnel of the Food and Drug Administration is bound to be influenced by the thalidomide tragedy. I have recently addressed a letter to Secretary Celebrezze expressing my thoughts on this matter. I am enclosing excerpts from this communication in order to avoid some duplication of my above remarks and respectfully, request that they be incorporated in the records of your committee.

Very truly yours,

ALFRED GILMAN, Ph. D.,
Professor and Chairman.

EXCERPTS FROM A LETTER ADDRESSED TO THE HONORABLE ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AUGUST 3, 1962

You have assumed your responsible office at a time when decisions relating to the control of new drugs are apt to be made on an emotional rather than an objective basis. The glaring publicity focused on the drug industry as a result of the hearings conducted by Senator Kefauver coupled with the unfortunate outbreak of phocomelia from thalidomide has created an atmosphere that borders on hysteria. Therefore, decisions made at this time are very apt to be ultraconservative.

There is an aspect of the approval and release of new drugs that is being little considered in the present climate. The decision not to release a candidate drug which later proves to have unexpected toxicity leads to deserved praise for those responsible for the judgment. However, the decision not to release a potential therapeutic agent may also have devastating effects on public health. In fact, "the drug that wasn't there" may be a greater tragedy than one which causes unexpected toxicity. It is my concern that the pendulum may swing to such an overcautious attitude that the number of "drugs that weren't there" may grow so large as seriously to impede the important contributions that pharmacology can make to medicine.

Please do not infer from the above remark that I am recommending a laissez faire attitude on the part of responsible governmental agencies. Careful toxicity studies should be demanded before any drug is given to man. More stringent toxicity studies are needed when a drug goes from initial clinical trial involving small numbers of patients under the care of trained and experienced investigators to a more extended clinical trial involving a large number of patients under the care of practicing physicians. But eventually the final decision to release a drug must be made. It is my opinion that the decision could best be made by a group of qualified experts.

Before the Department of Health, Education, and Welfare supports a research project costing a few thousand dollars, it is reviewed by a study section and council. But the decision to release a new drug is largely the responsibility of one individual. How simple it would be to set up review boards of highly qualified individuals to act in an advisory capacity to the Food and Drug Administration Ten such boards could cover the important areas of pharmacotherapy Represented on such review boards would be pharmacologists and clinicians who are expert and experienced in the particular area for which a drug is designed On the basis of this background of experience, a judgment could reasonably be made as to whether the therapeutic efficacy of a drug was sufficient to warrant the risk of some degree of toxicity. I know of at least one important drug which is being withheld from release because of the difficulty involved in such a decision.

I am sure that a program of this nature would receive the full support of basic scientists and clinicians. The number of new drugs submitted to these panels would not represent a great burden, especially if summaries of the material submitted were prepared by the present personnel of the Food and Drug

Administration. The advisory opinion of a panel of experts would do much to ease the burden of decision and help distribute the responsibility.

I trust the above remarks will merit your consideration.

Very truly yours,

ALFRED GILMAN, Ph. D.,
Professor and Chairman.

DRUG, CHEMICAL & ALLIED TRADES ASSOCIATION, INC.,
New York, N.Y., August 20, 1962.

Re H.R. 11581.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The Drug, Chemical & Allied Trades Association, Inc., is a New York nonprofit corporation. It represents almost 800 firms located throughout the United States. These member firms are engaged in the manufacture, distribution, and sale of drugs, cosmetics, and chemicals, and in the supply of essential materials and services to those industries.

Our association believes that the existing provisions of the Federal Food, Drug, and Cosmetic Act have worked well in practice. We are not opposed, however, to changes in this act which are desirable from the public health standpoint, and which do not impose unwarranted governmental control over the industries which are subject to that act. In this letter, we should like to set forth our views on H.R. 11581, and we request that this letter be made a part of the record of the hearings on that bill.

TITLE I

PART A

Requirement of adequate controls in manufacture, section 101

Our association has no objection to an amendment of section 501(*a*) of the Food, Drug, and Cosmetic Act (hereinafter called the "act") so as to cause a drug to be adulterated if the methods, facilities, and controls used for its manufacture, processing, packing, and holding do not conform to current good manufacturing practice so as to assure that the drug will have the identity, strength, quality, and purity that it purports to have.

We submit, however, that the test of what constitutes such "current good manufacturing practice" in any given situation should be an objective one, and should be left to the courts for determination. The test should not be left to administrative determination by the Secretary. This would create the very real possibility that improvements in manufacturing and packaging methods and techniques would be seriously retarded by a regulatory straitjacket.

We would urge that "personnel" be deleted from section 101 of the bill since individual competence can only be judged by a long and close observation. It is our belief that any attempt, through regulations, to standardize the qualifications of the various personnel engaged in the manufacture and control of drugs would produce unwarranted burdens for industry and produce serious injury to the careers of individuals.

We would recommend that subsections (ii) and (iii) of section 101(a) of the bill be deleted since their precise meaning is unclear. Furthermore, the apparent subject matter of these two subdivisions is already adequately covered by other sections of the act, particularly section 502(j) and the full provisions of section 501 and 502.

Premarket showing of new drug efficacy, section 102(a)

Many drugs are no longer "new drugs" under the definition presently contained in section 201(p) of the act because they are generally recognized as safe for use as recommended. The proposal that a drug must be generally recognized as "efficacious," as well as safe, would create great confusion as to whether the above mentioned drugs continue to be of new drug status. Furthermore, this proposal would seem to require clearance through the new drug procedures for every new use claimed for old drugs, even though the safety of the drug for such uses is unquestioned.

Our association believes that the existing definition of "new drug" is adequate, and that the proposed amendment thereto should not be adopted.

Section 102(b)

We submit that it is basically unsound to put FDA in a position to deprive the medical profession of newly developed drugs on the basis of that agency's views as to the effectiveness of such drugs. This is particularly so in view of the fact that physicians will often differ as to the effectiveness of a particular drug. If a drug is safe, and there is substantial evidence of its efficacy, the medical profession should not be deprived of the availability of the drug. Accordingly, we would have no objection to a revision of section 505 (a) and (d) of the act, which would allow FDA to refuse to make a new drug application effective if the applicant has failed to submit "substantial," though not necessarily preponderant, evidence that the drug has the effects which he claims for it.

Records and reports as to experience on new drugs, section 103 and 106

Our association is not opposed to an amendment to section 505(j) and 507(g) of the act which would provide FDA with clinical information, respecting drugs covered by effective new drug applications or antibiotic certificates or releases, of a kind reasonably needed by it. Any amendment to accomplish this, however, should require that the providing of such clinical information should be with due regard for professional ethics and should limit its review to licensed physicians. To complement such a provision, FDA should be obliged to provide to the manufacturer clinical information obtained by it.

As to the proposed amendment to sections 505(i) and 507(d), however, our association feels that such amendments are unnecessary. The existing provisions of those two sections are entirely adequate to deal with the subject of clinical investigations. As you know, on August 9, FDA proposed extensive new regulations covering such investigations. Those proposals are based on the authority contained in section 505(i) and 507(d) of the act. Industry is currently studying those proposals.

Procedural changes as to new drugs, section 104(a)

We submit that it would be a mistake to require FDA to approve or disapprove new drug applications rather than to permit or refuse to permit them to become "effective" as is presently the case. Such a change in FDA's function could very well result in undue caution on their part resulting in extensive delays in the availability of newly developed drugs.

The proposed revision to section 505(a) of the act in practical effect, relieves FDA of any obligation to decide, within a given period of time, whether or not to permit a new drug application to become effective. As a matter of fact, FDA could let 180 days pass without even looking at the application, and could then give applicant notice of a hearing on the vague ground of whether his application is "approvable." Moreover, FDA would be under no obligation to even commence such a hearing within any particular period of time. In our view, the existing provisions of 505(c) have worked well in practice and should not be changed other than to increase the initial period for action by FDA from 60 to 90 days. Comparable mandatory time periods for review are already contained in the pesticide amendment (sec. 408(d)) and the food additives amendment (sec. 409(c)) of the act and these provisions serve as a worthwhile precedent for continuing the existing time provisions in section 505(c).

Additional grounds for withdrawal or suspension of approval of new drug applications, section 104(b)

Our association agrees that the standards for suspending effective new drug applications should be liberalized somewhat. We submit that a mere finding of "substantial doubt" of safety or efficacy is too vague a ground on which to permit suspension. Rather, the applicable standard should be failure of the available evidence to meet the same tests that had to be met in order for the new drug application to become effective i.e., whether the drug is shown to be safe, and whether there is substantial evidence of effectiveness. Furthermore, the evidence justifying a decision by FDA to suspend a new drug application should be "new." FDA should not be allowed to change its mind on the basis of the evidence considered when it made the new drug application effective.

We urge that suspension of new drug applications not be authorized for failure to keep records, or make reports, or maintain manufacturing standards, since such failures can adequately be dealt with under other remedies already provided for in the act.

The provision of the bill which would authorize emergency suspension, prior to hearing, in some situations should also not be enacted since we are not aware of any situation wherein other remedies have not been adequate to terminate any immediate public health threat.

Certification of all antibiotics, section 105

Our association is opposed to the proposed extension of the certification requirement to all antibiotics for the following reasons:

1. Certification of antibiotics was conceived as a temporary measure at a time when production and control procedures had not advanced to a point where results were uniform. Currently antibiotics can be produced and controlled with as much uniformity as other drugs and hence the original need for certification no longer exists.

As an illustration of the advances that have been made in production of antibiotics, during fiscal year 1960 only 22 batches of the certifiable antibiotic drugs were rejected by FDA out of 16,601 batches tested.[1]

Even without the certification procedure, no reputable manufacturer would willfully market a batch of an antibiotic or other drug which was subpotent, unsafe or otherwise unfit for use, and if any company did there is ample authority in the act for proceeding against such substandard drug and its manufacturers. With or without certification, a manufacturer which distributes a substandard drug commits a criminal act by so doing.

2. Annual fees recently paid by industry for certification of the five currently certifiable antibiotics, and their derivatives exceeded $900,000. Proposals are pending to increase certification fees by 30 percent, to require FDA testing of nonantibiotic active components of certifiable antibiotics which will further increase fees and to substantially increase the testing and sampling performed on each batch. In 1959 approximately 150 man-years of FDA scientific, technical and administrative effort were devoted to certification.[1]

If the 30 antibiotics not presently certified, become subject to certification, it is conservatively estimated that industry's fees (disregarding the aforementioned proposed increases in fees) will increase to over $1,300,000.

3. Antibiotic certification is an extreme form of licensing power, giving FDA life and death control over the ability of a manufacturer to market certifiable antibiotic products. In view of the advanced state of the art of producing antibiotics, such burdensome control is not justified.

4. Extension of certification to the 30 noncertified antibiotics (several of which have been marketed for almost 12 years) would produce serious difficulty and confusion and undoubtedly would result in many unwarranted competitive advantages to manufacturers of the currently certified antibiotics.

Requests would presumably have to be submitted to FDA for regulations permitting certification of the hundreds of dosage forms containing the currently uncertified antibiotics, even though virtually all of these have previously been cleared by FDA under the new drug procedures and they are widely accepted by the medical profession. FDA would presumably have to re-review the data previously submitted with the hundreds of new drug applications covering these products. Furthermore, since most of these drugs are now off new drug status there have been some changes in formulation, manufacturing and testing procedures, etc. since the last new drug clearance was obtained, so that additional data may be required to be submitted and reviewed with respect to those changes. This reclearance will be unnecessary, wasteful of man-hours for Government and industry, and productive of great delay.

Biological drug, section 107(a)

Section 351(b) of the Public Health Service Act requires a showing of "safety, purity and potency" before a license can be issued for a biological drug. This bill would add a requirement of showing "efficacy."

Our association opposes this proposed new requirement. The current requirement of demonstrating "potency" is adequate and realistic. Earlier we mentioned the differences that exist among physicians as to efficacy of particular drugs. This is particularly true in the case of biologicals. It is generally possible to demonstrate that antibodies are formed after administration of a vac-

[1] Report to Congress by the Comptroller General entitled "Review of Enforcement and Certification Activities of the Food and Drug Administration, Department of Health, Education, and Welfare," dated September 1961

cine, but proving that a particular disease is thereby prevented is far more difficult.

Biological drugs, and the proper degree of Government regulation thereof, are most complex subjects. Our association feels that there is a need for an overall review of the provisions of both the Public Health Service Act and the Food, Drug, and Cosmetic Act pertaining to such drugs. We submit that such a review should be made in due course, and that it is unwise to deal with this subject in piecemeal fashion as this section of the bill proposes to do.

PART B. STANDARDIZATION OF DRUG NAMES

Authority to standardize names, section 111

Our association has no objection to giving the Secretary standby authority to designate a "single standard name" for a drug. However, he should not be authorized to exercise such authority until a reasonable opportunity has been afforded for the persons in charge of the compendia in which the drug is listed to select such a name. We would urge that the Secretary be precluded from selecting any name which would infringe trademark rights, and we would urge that procedures for selection of such names by the Secretary be subject to the hearing and review procedures of section 701 of the act.

Name to be used on label, section 112

Our association has no objection to a listing on the label of the "established name" of a drug and, if fabricated from two or more ingredients the "established name" of each active ingredient.

In the case of over-the-counter drugs, however, we do oppose the requirement of listing the quantity of each active ingredient since the quantitative formulas of many over-the-counter drugs are highly valuable trade secrets.

As to the requirement that the "established name" should be given precedence over and be in type at least as large and prominent as any trademark, we are most strongly opposed to such a requirement. It would seriously weaken the value of trademarks, and reduce the incentive to produce superior products. We submit that section 502(e) of the existing act deals very adequately with the subject of conspicuousness of required labeling statements.

PART C

Special control for barbiturates and stimulant drugs, section 121 and 122

Our association supports increased FDA control of amphetamines and barbiturates. We feel, however, that the provisions of the Dodd-Wiley bill (S. 1939) are better than this bill in a number of respects.

We do not however, favor the provision of this bill (subsection (c)) which would make "possession" an offense unless such possession is with intent to sell or otherwise distribute such drug. We also do not favor the grant of authority to bring other drugs under the controls which would apply to barbiturates and amphetamines.

Furthermore, in our view, the term "barbiturate" should not include drugs containing, in addition to any such barbiturate, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of barbiturate to cause a hypnotic or somnifacient effect; and the term "amphetamine" should not include drugs containing, in addition to any such amphetamine, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of amphetamine to cause a stimulating effect on the central nervous system.

The record-keeping provisions should not require a set form or forms for keeping the required records so long as the commercial or other records kept in the usual course of business contain the required information. Also it should not be required that the address of the patient be recorded in cases where the name and the address of the prescribing physician is shown on the prescription.

PART D

Amendments as to advertising, section 131

Our association fully supports the principle that full and complete information necessary for the use of drugs should be readily available to physicians. We submit, however, that "advertising" is not the manner in which such information should be made available. It is not, and it should not be the purpose

of advertising to give physicians full information on how to use the drugs. Moreover, in the case of many drugs, such information is so voluminous that it would be impractical to include it in advertising. Our association, therefore, opposes the provisions of section 131 of the bill. However, hearings in mind that the purpose of advertising is merely to remind physicians of the availability of a drug, we would have no objection to a provision which would require medical journal advertising to contain a statement to the effect that physicians should consult the manufacturer's literature for information concerning possible contra-indications and side effects.

TITLE II

Factory inspection, section 201

In the case of drugs, our association supports an extension of FDA factory inspection authority. We submit, however, that any new law should provide adequate safeguards against disclosure of confidential information and undue interference with the right of management to operate its own enterprise. Accordingly, the articles subject to inspection should be limited to those having a material bearing on the specific violations of the law. Furthermore, it should be specifically provided that the authority to inspect shall not extend to (*a*) financial records, (*b*) sales records, (*c*) pricing records, (*d*) personnel records, (e) records of research activity, and (*f*) complaint files.

In the case of complaint files, the limitation need not apply to communications from licensed practitioners and institutions, provided that inspection of such data be conducted with due regard for and consistently with the professional ethics of the medical profession, that access thereto be available only to licensed medical personnel of the Department, and that corresponding information held by the Secretary be made available to medical personnel of the drug manufacturer.

We are opposed to the extension of factory inspection authority proposed by section 201 of the bill. That section would increase the scope of such authority to such an extent as to raise questions of constitutionality, especially considering the fact that this act contains criminal penalties. Apart from those questions, however, we submit that it is wrong in principle to authorize virtually unlimited inspection authority. Such broad powers would seriously jeopardize the many valuable trade secrets possessed by members of all industries subject to the act.

Confidentiality of information obtained by inspection, section 202

We favor the proposed amendment of section 201(j) of the act, which would prohibit disclosure of any information obtained by inspection. We submit, however, that the proposed insertion of the words "as authorized by law" should be changed to read "as required by law."

It is our understanding that the Pharmaceutical Manufacturers Association intends to propose that the act be amended so as (*a*) to prohibit counterfeiting and (*b*) to require registration of drug manufacturing establishments and to require inspection of such establishments at least every 2 years. We support those proposals.

We are most appreciative of the opportunity to express our views on the provisions of this bill which are of such vital concern to the members of our association.

Respectfully submitted.

WILLIAM J. SCHIEFFELIN III, *President.*

THE REUBEN H. DONNELLEY CORP.,
New York, N.Y., August 22, 1962.

Re. H.R. 11581.

HON. OREN HARRIS,
Chairman of the Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

MY DEAR MR HARRIS: Once again, as we did in our letter to you of November 15, 1961, we would like to protest that part of H.R. 11581 which would require full disclosure in medical journal advertisements.

As publisher of six medical journals, and particularly as publisher of "Modern Drugs," which has for the past 25 years presented product brochures and complete descriptions of drugs, it seems to us to be entirely unnecessary for advertisements in this publication to repeat what is already presented in the text pages of the publication.

Last year we published over 7,500 pages of scientific literature for the information of physicians. This literature constantly gives the physicians the very latest in cautions and contraindications. Advertising carried in our pages is largely in the form of "reminder" copy.

We believe that if manufacturers are forced to pay for full disclosure advertising this will, in turn, have a decidely adverse effect on allocation of money for the research so necessary to the saving of lives.

We believe, for the good of all, that the requirement for full disclosure in advertising should be stricken from the bill.

May we request that this letter be made a part of the record.

Sincerely yours,

THE YORKE MEDICAL GROUP,
PLINY A. PORTER, *Publisher.*

AEROSPACE MEDICAL ASSOCIATION,
Washington D.C., August 31, 1962.

Hon. OREN HARRIS,
Chairman, Interstate and Foreign Commerce Committee,
The House of Representatives, Washington, D.C.

DEAR MR. HARRIS: In view of our committed responsibility of guarding the safety, health, and welfare of our men in aviation and astronautics both in the air and on the ground, we take this opportunity to call to your attention the possible hazards of the advertising provisions of H.R. 11581. Such requirements as set forth in the measure could have serious effect on the initiative of investigation so necessary on the part of all of us who practice medicine.

I refer to the intuitive desire by the physician for complete information on any particular medical procedure or the prescribing of any specific drug. Before a physician prescribes either old or new pharmaceuticals, he is expected to first inform himself fully on all aspects of efficacy, side effects, and contraindications. We are reluctant to either assume or believe this information can be presented in advertising space of a size available in medical journals. Thus, you can see that the details necessary in the professional literature could not possibly be included in today's pharmaceutical advertising. We do not want to encourage the substitution of advertising for studying the scientific literature. Basically journal advertising of drugs for prescribing is a means of alerting the physician to their availability and basic therapeutic qualities. Such advertising has never been intended to say, "This drug will do so and so. Go ahead and prescribe it."

Much information on drugs becomes a part of medical society meetings, hospital staff meetings, and seminars. Here knowledge on new drugs is disseminated by lecture, discussion, and experience reporting. Under the proposed requirement it is possible that in many instances much of the information bearing on all aspects of the drug could not be printed because of limitation of space and it would most certainly, in some instances, result in the prescribing of the drug without all the pertinent data needed to insure the safety of the patient.

Much has been accomplished in many other features of the measure. However, we sincerely believe that to allow the section regarding the advertising provisions to remain would detract from and weaken the beneficial provisions.

Sincerely,

WILLIAM J. KENNARD, M.D.,
Executive Vice President.

FELTON CHEMICAL CO., INC.,
Brooklyn, N.Y., August 28, 1962.

Re H.R. 11581, proposed factory inspection provisions.

Congressman OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

Congressman VICTOR L. ANFUSO,
House Office Building,
Washington, D.C.

DEAR SIRS: The writer is an attorney at law, house counsel for Felton Chemical Co., Inc., assistant secretary of that company, and has been actively engaged in the essential oil and basic perfumery business for upward of 30 years. Our company is a member of the Essential Oil Association of the U.S.A. and the writer is a member of its legislative committee. As such, the writer is thoroughly familiar with the statement prepared by the Essential Oil Association of the U.S.A. and presented to this committee by Mr. Dittrich, its president, on August 23, 1962, as well as the statement presented by Mr. Eugene P. Grisanti, on behalf of International Flavors and Fragrances, Inc., a firm similarly situated.

On behalf of Felton Chemical Co., Inc. we wish to enter upon the record of the proceedings of the House Interstate and Foreign Commerce Committee our objections to and protest against the inclusion of the proposed "factory inspection" amendments contained in H.R. 11581, upon the facts and for the reasons given in the aforesaid statements of Mr. Dittrich and Mr. Grisanti.

Your attention to and consideration of the foregoing is most sincerely urged.

Respectfully yours,

FRANK BRUMBURGH,
Assistant Secretary.

BRAND NAMES FOUNDATION, INC.,
New York, N.Y., August 17, 1962.

Subject: H.R. 11581.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
New House Office Building, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The undersigned, a membership organization incorporated in New York State, respectfully wishes to present to you and your committee the view that certain provisions of H.R. 11581, being considered by your committee, are contrary to the public interest.

The foundation was incorporated December 11, 1943, as the Brand Names Research Foundation, Inc. Its name was changed with the approval of the State of New York, Division of Corporations, September 4, 1946.

The membership of this cooperation is listed in a printed roster, a copy of which accompanies this letter. You will note that it is comprised of commercial organizations manufacturing products sold in general distribution with advertised trademark identifications, professional advertising agencies, and the several media of communication.

Your attention further is called to the fact that although some of the companies making and distributing pharmaceutical products participate in our endeavors, they are a very small portion of our membership and account for less than 1 percent of our total revenue. Members of our board of directors speaking for the drug industry, including advisory, nonvoting directors, are only 4 in a total of 53.

PURPOSE OF BRAND NAMES FOUNDATION

The purposes of this corporation, as stated in our certificate of incorporation, are as follows:

(*a*) To advocate and advance the principle and philosophy of freedom of choice, inherent to free enterprise, and freedom to develop better products and receive due reward for results achieved.

(*b*) To defend the proven, typically American system of merchandising, using advertising of trademarked and branded products and to use any proper steps deemed necessary or desirable to advance the system to even greater usefulness.

(c) To create greater understanding on the part of the general public of the significance of trademarks and brand names in the exercise of freedom of choice.

(d) To demonstrate to an increasingly larger proportion of the public and to Government officials the jealous care shown by ethical manufacturers to maintain the highest standards of quality and value of their trademarked or branded products and the desirability of such care in each individual instance with consumers acting as their own judges.

(e) To carry out by every lawful means a campaign with respect to the desirability and value of trademarks and brand names, and to do any and all things lawfully permitted in furtherance of the foregoing purposes and objects.

CONVICTIONS

The members of Brand Names Foundation, Inc. believe that the manufacture and distribution of brand-named products result in a continued concern for public approval and patronage of trademarked items. Thus, there is a constant concern for consistency of quality and, through research, a constant aspiration for product improvement.

ACTIVITIES OF THE FOUNDATION

During the more than 19 years of its existence, in behalf of its diversified members, this corporation has engaged in continuous educational and promotional activities. The purpose of these has been to heighten the public's awareness that, no less than they are a means of facilitating the distribution and selling of products, manufacturers' brand names are a service and guarantee of responsibility and satisfaction to their ultimate purchasers.

OBJECTIONS TO THE PROPOSED LEGISLATION

We respectfully bring to your attention our opinion that certain aspects of H.R. 11581 ultimately will be hurtful to consumer interests. Although no comment is offered herein on the other provisions of the bill, this should not be interpreted as either approving or disapproving such other provisions:

Section 111

This would grant to the Secretary of Health, Education, and Welfare the right to designate a "standard name" for a drug which would be the "established name" for such drug.

The foundation has no objections to the standardization of names as such for any category of products. However, we believe that there should be a specific prohibition against the adoption of any valid trademark as the standardized name of any product. Section 111, as written, does not contain any limitation upon the name that may be selected by the Secretary and thus placed in the public domain. Potentially the affected name nevertheless could be a valued trademark.

A dangerous precedent would be set if a manufacturer were faced with the possible loss of exclusivity in his trademark by governmental fiat. Accordingly, it is our suggestion that section 111 should contain an express provision prohibiting the Secretary from designating as the standard name for a drug any valid trademark.

Section 112(a)

Brand Names Foundation also objects to section 112(a) which, as written, would require a drug manufacturer to give the "established name" of his drug precedence in position over the trademark or brand name, and use it in type at least as large as such trademark or brand name. This provision's admitted purpose is to encourage the prescribing and sale of drug products by their generic designations rather than by their trademarks.

This concept and precedent, once established, could at another time be applied to any other category of products that consumers purchase and use.

Thus, "drip-dry" shirts could be made an identification equal to or dominant over the trademarks or brand names now identifying the distinctive craftmanship, style standards, and qualities of several preferred brands.

"Pressed wallboard" could be an indication equal or dominant to the brand names of the wide variety of manufactured products that serve structural purposes.

"Vegetable soup" could, by the precedent of section 112(a), identify a substantial variety of products that today are represented by names like Campbell, Heinz and others, each representing distinctive flavors and ingredients. The housewife would be unable to serve her family according to its palate preferances if she followed only commonly established descriptive names.

Your committee readily will recognize innumerable other potential analogies.

The proposed radical departure from the present reliance on reputation could only result in the reduction or elimination of incentive to attract consistent patronage, and thus the deterioration of quality and of aspiration for progressively greater excellence now dominating the manufacturers of consumers' goods.

This provision, if enacted, would set a precedent for product mediocrity and encourage and protect the counterfeiter and substituter.

The community of industries and service organizations represented in Brand Names Foundation respectfully calls the committee's attention to the fact that of all the kinds of consumer products, those consumed internally could be the most dangerous among which to encourage mediocrity or to discourage the prevailing aspiration for excellence. In the manufacture of drug preparations, the trademark symbolizes not only the active ingredients, but also the quality, purity, and efficacy of the end products.

In the light of the foregoing conclusions, we again respectfully urge the committee to reconsider these provisions of H.R. 11581 with respect to their ultimate effect on consumer interests and the precedents they could set affecting the service of the traditional competitive trademark system.

Very truly yours,

HENRY E. ABT, *President.*

NEW YORK UNIVERSITY,
SCHOOL OF LAW,
New York, N.Y., June 26, 1962.

HON. OREN HARRIS,
Chairman, Interstate and Foreign Commerce Committee,
U.S. House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: On Friday, June 22, 1962, I attended the hearings of your Committee on Interstate and Foreign Commerce, in hopes of testifying before you on House bill H.R. 11581–87th Congress, 2d session. Unfortunately, the short time available to the committee made it impossible for me to be called as a witness. Following your suggestion at the close of that hearing, I am, therefore, taking the liberty of submitting to you a number of comments on the bill which I otherwise would have made orally. In thus commenting on the bill, I am stating my views as a professor or criminal law (at New York University), and not as a representative of any organization or association. My interest in the bill is that of a citizen who dislikes adulterated food, because I may have to eat it, and as a law professor who dislikes adulterated laws, because I may have to teach them.

First of all, permit me to commend the committee for the thorough way by which it investigates the need for further legislation in this field.

Next, permit me to note that everybody's concern centers on four points which seem beyond dispute. These I propose to discuss:

(1) Everyone agrees that the existing act and the proposed bill are full of "Weasel" words, vague standards, and uncommon meanings. Simply by way of example, what does the word "unsafe" mean in connection with section 402 2(c)? Through a maze of cross references, we learn ultimately that "unsafe" means failure to comply with the Secretary's view as to what is consistent with the public health, as expressed in a regulation issued for the promotion of honesty and fair dealing in the interest of consumers.

I could go on ad infinitum to point to a multitude of vague concepts and standards in the act. As a theoretician of the law, I cannot understand why a Nation as intelligent as ours cannot produce a legal draftsman capable of drafting bills which tell those regulated thereby what is expected of them. But let us assume that we cannot avoid the vague standards. Then I would think that we should go to pains to prevent possible abuses arising from such vague standards, namely by limiting bureaucratic discretions. Does the act do that?

No, and that leads to the second point.

(2) Broad discretions are joined so tightly with the vague standards that no man can put them asunder. The Secretary himself has enormous discretions. Thus, he might promulgate regulations whenever, in his judgment, such action

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will promote honesty and fair dealing in the interest of consumers, etc., etc. The proposed bill is intended to enlarge these discretions. Is is necessary that the administration be granted such vast discretions? I personally seriously doubt that. But let us assume that the broad discretions are as necessary as the vague standards. This leads us to the third issue.

(3) Should the Secretary be invested with police powers greater than our armed law officers possess in preventing rape and murder? No police officer is vested with the power "at all reasonable times" to inspect the bedrooms of American citizens, although, according to Dr. Kinsey, most of such bedroom violations of the law constantly take place. Or does the police have the power to make inspection of houses and rooms therein even if they suspect that a dead body or a machinegun might be hidden there? No, they will have to obtain a warrant upon evidence sworn to, establishing probable cause that a crime has been committed therein. But H.R. 11581, in section 201(a), is the first example in American history in which our constitutional standards, developed on the basis of the fourth amendment, are completely set aside. This section, in effect, legislatively creates an irrebuttable presumption of facts and a presumption of an oath attesting to these facts, that all American food and drug manufacturers, etc., are probably continuously engaged in the commission of crimes in their establishment, for it creates the basis for entrance, search for evidence of crime, and seizure of such evidence without any formality. The committee is familiar with the cases in which the statutory right of health inspectors to inspect premises was upheld. In none of these cases were health inspectors empowered to search for the evidence of crime. There can be no doubt whatsoever that the authority which this act proposes to establish in the Food and Drug Administration is in violation of the fourth amendment to the Constitution. But apart from the fact that the provision is unconstitutional, there is inherent in this provision an incredible insult to an essentially law-abiding industry. No other industry has ever been deemed, impliedly or expressly, to be constantly engaged in the commission of crime, so that searches for evidence of crime may take place without warrant or warning. If the committee feels that the FDA needs particularly broad powers of search and seizure, for the protection of the public health, I think it is absolutely necessary that an incrimination-immunity proviso be added to the provision, to the effect that any evidence seized cannot be used in any criminal prosecution against any person or company from whom such evidence has been taken. I still maintain, however, that the effect of this provision is to antagonize an industry which otherwise would, in all probability, cooperate eagerly with the Food and Drug Administration.

(4) My last point pertains to the penalty section of the Federal Food, Drug and Cosmetic Act, especially section 333 (a) and (c), which the presently proposed amendments do not touch upon, but should.

On many occasions I have pointed out, in print and spoken word, that the absolute liability feature of this penalty section is repugnant to our American sense of injustice and flies in the face of every experience gathered in eight centuries of common-law history. Absolute liability means that the guilty and the innocent violator are punished alike, that the careful and the careless entrepreneur are both subject to punishment. Nothing can be plainer than that punishment of the careful will create frustrations. Obviously, if a man can be proven guilty, he should be severely dealt with, preferably by imprisonment rather than fine. But if a man is not guilty, he deserves an acquittal regardless of what happens to a tainted product which may have been innocently produced. It is no answer to say that the Food and Drug Administration will not pick the truly innocent violator for prosecution. In the first place, they have done so, as the long list of cases cited in the annotation of 21 U.S.C.A. section 333 indicates. In the second place, impunity of innocent persons should not be a matter of administrative graces but a matter of right. The law itself should make this clear. I urge your committee, therefore, to reconsider section 333 and to insert in line one, behind the words "any person who" the words "intentionally or recklessly." This, in turn, would make it possible to drop the entire subsection (c) with its currently wholly inadequate list of exceptions to the enormous sweep of otherwise absolute criminal liability.

I should be pleased if my few comments will be of help to you and the members of your committee, to whom I express my sincere respect.

Faithfully yours,

GERHARD O. W. MUELLER,
Professor of Law.

KINNEY & CO., INC.,
Columbus, Ind., June 18, 1962.

HON. ANCHER NELSEN,
House of Representatives,
Washington, D.C.

DEAR MR. NELSEN: Thank you for taking time from your busy day to visit with me last Thursday. I appreciate your attentive consideration to my point of view on certain provisions of the Harris bill, H.R. 11581.

You suggested that I write you on the subject and that you would make this letter a part of the record of the hearing on this bill.

Kinney & Co., Inc., is "one of the little fellows" in the industry. Our sales are less than a million dollars annually. We are, therefore, vitally interested in any provision of the proposed new drug law which would be particularly damaging to small companies.

As a small pharmaceutical company, we are deeply concerned about the proposed provision that the generic name of a product be given precedence in position over the trademark. The opinion has been expressed that drug products should be identified by generic names rather than trade names, the theory being that this would give the small drug manufacturer an opportunity to compete more effectively with the larger companies. The added competition anticipated is theoretically supposed to reduce the cost of drug products.

We are convinced that any legal provision that would tend to eliminate or downgrade the use of trademarks on drug products would also tend to eliminate the small drug manufacturer. The only chance for the small drug manufacturer to exist is through the development of worthwhile products which he can market under a trademark. Without a trademark, a small pharmaceutical manufacturer who develops a product of merit and markets it under the generic name would soon find that his business was gobbled up by larger manufacturers who would soon be selling the same product under the same name. The small manufacturer without any trademark protection could not maintain his business against the massive production distribution and promotional facilities of the large drug manufacturer.

The active competition of small pharmaceutical companies, each striving to carve a niche for itself, has resulted in many worthwhile contributions to medicine and to the public. We are convinced that the end result of generic drug products as against trademarked drug products would be the elimination of most small and medium size drug companies and the concentration of drug manufacturing and distribution in a few giant firms.

Such a concentration of drug manufacturing and distribution would not be a desirable objective from any standpoint. I hope your committee will take into consideration the destructive end result of this ill-conceived provision to hamstring the use of trademarks on pharmaceutical products.

Very truly yours,

H. S. KINNEY.

TRAPPE FROZEN FOODS CORP.,
Trappe, Md., June 25, 1962.

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR SIR: We, as a frozen food packer, are vitally concerned with the provisions of proposed legislation in title II of H.R. 11581. The purpose of this letter is to go on record as opposing the amendment which would modify the Federal Food, Drug, and Cosmetic Act to expand factory inspection powers.

The statement submitted to your committee by the National Canners Association has our full support. There is very little we, as an individual packer, could add to this excellent statement, which would not be a repetition of what has already been expertly presented.

The general trend of most Government bureaus, departments, and agencies to gain more and more powers and control over the individual citizen as well as business is evidenced by the unwarranted powers provided by H.R. 11581.

We sincerely hope that, for the benefit of the country as a whole, this bill will never get out of committee.

Very truly yours,

G. K. CALVERT.

NATIONAL BAKERY SUPPLIERS ASSOCIATION,
June 21, 1962.

MR. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, House Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: The National Bakery Suppliers Association in behalf of its members who are the largest and most economically important in their industry, respectfully suggest that the proposed extension of the factory inspection power under the Federal Food, Drug, and Cosmetic Act, as proposed in H.R. 11581, is not warranted.

Our industry is not averse to factory inspection which is reasonably required for an effective administration and enforcement of the law to insure shipment of safe and clean foods properly labeled. However, we respectfully submit that experience under the existing law abundantly demonstrates that the present powers are fully adequate, at least insofar as the production and distribution of foods is concerned, to insure this objective.

We believe that granting of the sweeping administrative power as proposed in the bill will not contribute anything not now available and reasonably required for effective administration and enforcement of the act. For example, all foods and food ingredients which are not generally recognized as safe have to be approved for distribution in interstate commerce by formal regulation. The powers implicit in the pesticide chemicals amendment, the food additives amendment and the color additive amendments of the law, coupled with the present factory inspection power, completely cover all facts reasonably required to determine food safety.

In addition to the specific powers included in these amendments to insure food safety, the present law authorizes the entry and inspection of "any factory, warehouse, or establishment" in which commodities subject to the act are manufactured, and to inspect all of such premises and "all pertinent equipment, finished or unfinished materials, containers and labeling therein."

Under these provisions a duly authorized inspector is entitled to, and history of experience shows that he has always been getting, all information which can have any possible bearing on likely safety, cleanliness, and proper branding of foods. Samples of the raw materials or of the foods at various stages at its preparation, as well as samples of every item of printed matter which is on the container of a food or accompanies a food is available. Indeed it is impossible to conceive of any additional information needed to insure the indicated objective in the production and distribution of foods.

However, while the sweeping open-end provisions proposed in section 201 of H.R. 11581 will contribute very little, if anything, additional to information needed to achieve these statutory objectives, they would grant authority to demand delivery to an inspector of "all things" located in the establishment, including outside consulting laboratories engaged in highly confidential research "including records, files, papers, processes, controls and facilities" bearing on whether commodities which are not eligible for shipment in interstate commerce are being manufactured in such plant "or otherwise bearing on violations or potential violations of this act." This, it is submitted, would grant complete open-end authority to require submission of all sorts of highly confidential information, such as details regarding confidential formulate, processes, new products research, complaint files, personnel files, and the like, none of which would provide any real assistance in determining facts required to come to a conclusion as to whether a food is or is likely to be unsafe, unclean or misbranded.

It is understood, we are certain, that Federal inspectors are human beings, not some form of machine or tape that can be locked away in a Government vault. They are human beings, with all the freedoms this great country of ours insures its citizens. One of which is the freedom to change his job—to move from Government employment to private industry.

As stated, our industry is not averse to any inspection, or to providing any information, reasonably required to assure this objective. However, at least insofar as the food industry is concerned, no need whatever has been shown for the suggested extension of the inspection power. If the Department has been denied certain information which it can demonstrate to the satisfaction of this committee as being reasonably required in the effective enforcement of the act, then that area of need should be spelled out precisely by indicating the specific additional information required, so that this committee may then judge the merits on specifically claimed needs.

The problem, if one exists, should not be approached by adopting sweeping open-end legislation which will prove a burden to the reputable members of the industry but will be unenforcible against any member choosing to disregard it.

Respectfully submitted.

JOHN W. ALLEN, *President.*

NATIONAL FEED INGREDIENTS ASSOCIATION,
Des Moines, Iowa, August 16, 1962.

To: Mr. W. E. Williamson, Clerk, House Committee on Interstate and Foreign Commerce, the House of Representatives, Congress of the United States, Washington, D.C.

From: National Feed Ingredients Association, Des Moines, Iowa.

Subject: H.R. 11581 (title II), that portion of the bill to amend the Federal Food, Drug, and Cosmetic Act with respect to strengthening of factory inspection authority.

DEAR SIR: The National Feed Ingredients Association and all its members urgently recommend to the members of the House Committee on Interstate and Foreign Commerce of the Congress of the United States to reject the provisions of titel II of H.R. 11581 introduced by Congressman Oren Harris, of Arkansas, on May 3, 1962.

The association and its members have come to this conclusion because the authority given the administrative authority is so broad as to be an invasion of the liberties guaranteed by the Construction of the United States and because the administrative authority can achieve the same end results by due process of law.

Since the same results can be achieved by the administrative authority by due process of law, we urge that the House Committee on Interstate and Foreign Commerce of the Congress of the United States reject the provisions of title II of H.R. 11581.

Sincerely yours,

I. LEVIN, *Executive Secretary.*

AMERICAN NURSES' ASSOCIATION, INC.,
New York, N.Y., August 20, 1962.

Representative OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
U.S. House of Representatives, Washington, D.C.

DEAR MR. HARRIS: The American Nurses' Association has an interest in current hearings on drug legislation and supports Federal legislative proposals that seek to make readily available to all concerned professional practitioners current and accurate information on drugs.

Nurses do not prescribe drugs since this constitutes the practice of medicine, but under the licensing laws of the various States, nurses are permitted to administer medications under a physician's order. In carrying out this function, a nurse is legally required to understand the cause and effect of the order she executes.

The American Nurses' Association endorses the "Statement of Principles Involved in the Use of Investigational Drugs in Hospitals" which was developed by the American Hospital Association and the American Society of Hospital Pharmacists. The third principle of this statement is: "When nurses are called upon to administer investigational drugs, they should have available to them basic information concerning such drugs, including dosage forms, strengths available, actions and uses, side effects, and symptoms of toxicity."

We will not comment on other proposals in the bill you are considering since these are outside our area of competence.

We would appreciate having this letter included in the record of hearings on H.R. 11581.

Sincerely yours,

JUDITH G. WHITAKER, *Executive Director.*

WASHINGTON, D.C., *August 20, 1962.*

Re H.R. 11581.

Hon. OREN HARRIS,
Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: As you may be aware, the Society of the Plastics Industry has previously requested time to appear before your committee to express its views with respect to the factory inspection provisions in H.R. 11581. On the strength of the indications in your announcement that the committee's interest is now in legislation relating to drugs, and with cognizance of your request that "organizations * * * be mindful of the time limitation under which the committee will operate," the society is not presently planning to appear.

We realize that the Senate committee which has been working on similar legislation has already amended its proposals to limit the factory inspections provisions to drugs. We are also aware of the President's suggestions that H.R. 11581 should be similarly amended.

We would like it clearly understood that we are still interested in any factory inspection proposal which might relate to food additives or other areas in which the society might have an interest, so we should appreciate being given an opportunity to present our views at a more appropriate time when and if these matters are to be further considered.

Respectfully submitted.

JEROME H. HECKMAN,
Counsel for the Society of the Plastics Industry, Inc.

PET FOOD INSTITUTE,
Chicago, Ill., May 31, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR SIR: The Pet Food Institute, a trade association comprised of over 50 manufacturers of pet foods and their suppliers, respectfully wishes to express its opinion with respect to the proposed broadening of factory inspection powers in the Federal Food, Drug, and Cosmetic Act. A review of our membership indicates that the pet-food industry has real misgivings concerning the true need for the expanded powers proposed by H.R. 11581.

These misgivings do not refer to the general regulatory principles of the FDA nor to the manner in which these principles are applied. As a matter of fact, the Pet Food Institute, representing one of the more important segments of the food industry, has felt that such principles generally have been fairly and reasonably administered to the distinct well-being of the general public. Our association has consistently approved and applauded the objectives of the Federal and State food, drug, and cosmetic laws. However, the current proposal to provide FDA inspectors with power to examine financial and personnel records and files seems to have scant reference to the intention and spirit of such legislation; surely no excuse can be set forth for an examination of records on research and development of product.

To be more specific, the past record of the food industry in general, and the pet-food industry in particular, indicates that the present provisions of the Food, Drug, and Cosmetic Act are more than adequate. Increased factory inspection powers would merely create additional and unnecessary requirements that would be needlessly time consuming and expensive to the pet-food industry, and therefore to the consumer.

It has been regular practice among pet-food manufacturers to make available all information needed by the FDA on a cooperative and willing basis wherever there has been any question regarding the wholesomeness or sanitation of product. Extended authority will very likely result in the need for the pet-food manufacturers to incur additional cost to operate in order to provide information asked for but of very questionable value insofar as the consumer is concerned, either from the point of view of health, sanitation, or deception.

There is no question that H.R. 11581 would open up for review confidential financial and product information having no bearing on product quality, safety, or possible deceptive practices. There has been no demonstrated need for additional authority by which a more effective enforcement of the Federal Food, Drug, and Cosmetic Act would be obtained and which is not available to it

under the present authority. If any such need can be demonstrated for extension of the authority in specific areas pertinent to the purpose of the act, legislation restricted to such specific areas of inquiry can be proposed for study.

The Pet Food Institute feels that experience, not only in its own industry, but in the food industry in general, has not been such as would justify the sweeping factory inspection powers now sought which include within its scope power to demand information regarding products and personnel rightfully considered confidential.

The board of directors of Pet Food Institute, after careful study, has adopted a resolution opposing the proposed amendment to the Federal Food, Drug, and Cosmetic Act expanding factory inspection powers. We, therefore, wish to place ourselves on record with your committee urging that sections 201 and 202 be deleted from H.R. 11581 prior to submission of this bill to the House of Representatives for a vote.

Thank you for your attention to this matter. We shall be happy to provide additional information in support of the above points if you so desire.

Sincerely,

HENRY A. BUCKLIN, *President.*

AMERICAN SYRUP & PRESERVING CO.,
Nashville, Tenn., May 31, 1962.

Representative OREN HARRIS,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: With reference to H.R. 11581, I note that the National Preservers Association, of which our company is a member, and of which I am an officer and a member of the board, has taken a position opposing certain sections of this bill. mainly sections 201 and 202.

This company, and I, would like to go on record as supporting wholeheartedly H.R. 11581, as written, and urge that your committee, after full consideration of it, give it speedy approval.

May I add that the only way I think that this bill could be improved would possibly be to emphasize the adjective, "reasonable," that is used in part 2 of section 201. This should protect individuals from any undue exercise of powers by administrative agents of the Federal Food and Drug Agency.

I would like further to add that we feel that the highly sophisticated new foods, drugs, and cosmetics make it imperative that H.R. 11581, in its substantial form, be hurriedly enacted.

Respectfully yours,

WILLIAM MARTIN.

SEEMAN BROS., INC.,
New York, N.Y., May 29, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: I wish to express my opposition to the enactment in its present form of H.R. 11581, now before the House Committee on Interstate and Foreign Commerce. I would find the bill more acceptable if certain reasonable changes were made in it.

The bill is obviously a response to unique facts disclosed during investigation of the drug industry by Senator Kefauver's Antitrust Subcommittee. The food industry was not involved in that investigation. The bill gives inspectors under the Federal Food, Drug and Cosmetic Act unreasonable and excessively broad powers to inspect factories. These powers are clearly unrelated to, and go far beyond, those purposes of the act aimed at preventing adulteration and misbranding in the manufacture of food.

The food and drug industries are different and have different problems and characteristics. Therefore, legislation intended for the drug industry should not include the food industry automatically and except for the most compelling reasons.

Accordingly, I strongly urge you to oppose the application of the factory inspection provisions of H.R. 11581 to the food industry. This can best be accomplished at this time by suporting a severance of the factory inspection provisions

of the act so that the food and drug industries will be treated separately and in accordance with their own distinctive problems.

Sincerely,

PAUL E. ZEGER,
Vice President, Finance and Treasurer.

JUNE 1, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR REPRESENTATIVE HARRIS: The Popcorn Institute is a national trade association made up of the processors and distributors of popcorn. The membership comprises more than 40 companies doing business throughout the United States. Members of the Popcorn Institute are vitally concerned with a measure pending before your committee designated as H.R. 11581. The members of the institute, after careful study, have adopted a resolution opposing the proposed amendment to the Federal Food, Drug, and Cosmetic Act expanding factory inspection powers. We wish to outline their objections to the proposed expansion of factory inspection powers, and respectfully request your consideration thereof.

Under the provisions of H.R. 11581, FDA inspectors whose previous duties have been limited to seeing that the public is protected as to food and drug products, would be given the additional right to probe into financial and personal records as well as to delve without reservation into confidential records concerning research and development of products. Our industry does not believe these powers are remotely connected with the statutory objective and with the preservation of the public interest. We do not believe that they can be classified as being essential for the protection of the public interest.

Questions of fact as to wholesomeness, preservation of health, and the prevention of deception are sound purposes for which the Food and Drug Administration should be given every necessary tool, but we respectfully submit that the review of confidential financial and research information have no bearing on quality of product, safety, or marketing practices.

We do not believe that the subject bill is needed to permit the effective operation of the FDA; we do not believe it is either necessary or in the public interest. We therefore respectfully request that the proposed sections 201 and 202 be deleted and that the agency powers and authority not be expanded into matters wholely apart from the statutory objectives.

If we may provide you or your committee with any additional information which would be helpful, we would be happy to do so.

Respectfully yours,

WILLIAM E. SMITH.

FROZEN PEA COUNCIL,
Chicago, Ill., June 12, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The Frozen Pea Council is a national trade association comprised of frozen pea processors. Twenty-one companies throughout the country are active members. Recently, member companies have become vitally concerned about the measure now before your committee, which is known as H R 11581. The board of directors of the council wish to go on record with this letter as opposing the amendment which would modify the Federal Food, Drug and Cosmetic Act to expand factory inspection powers.

Presently, inspectors are empowered to protect the public concerning wholesomeness, accurate labeling, and deceiving practices relative to the marketing of food and drug products. All possible aid should be rendered to insure enforcement of these regulations.

H R 11581 empowers FDA inspectors to investigate financial and personnel records, and to go into confidential files concerned with company research and product development. The proposed powers are not related to statutory objectives and protection of the public interest.

The Frozen Pea Council respectfully submits the following points for your consideration:

(1) The review of confidential financial and research information has no bearing on quality, safety or marketing practices.

(2) The proposed bill is not needed.

(3) The proposed bill is not to be desired because it grants unwarranted powers.

(4) Proposed sections 201 and 202 should be deleted because the agency should not be given power over matters apart from statutory objectives.

The council and individual members will provide you and your committee with all possible assistance on this subject.

Sincerely,

FRANCIS C. KERR, *Executive Director.*

NATIONAL PECAN SHELLERS & PROCESSORS ASSOCIATION,
Chicago, Ill., May 31, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

SIR: The National Pecan Shellers & Processors Association is a trade association comprised of the shellers and processors of pecans. It is made up of more than 65 firms doing business throughout the United States. Its members are vitally concerned with a measure pending before your committee and designated as H.R. 11581. The board of directors of the association, after careful study, has adopted a resolution opposing the proposed amendment to the Federal Food, Drug, and Cosmetic Act expanding factory inspection powers and pursuant to their authority, we wish to set forth for your earnest consideration their objections to the proposed expansion of factory inspection powers.

Under the provisions of H.R. 11581, FDA inspectors, whose responsibilities and duties have heretofore been limited to seeing that the public is protected as to food and drug products, would be given the right to probe into financial and personnel records and to delve without reservation into confidential records relative to research and development of product. These powers are so remotely connected with the statutory objective and with the preservation of public interest that they cannot be defended as essential—or even reasonable—to the protection of the public interest.

Questions of wholesomeness, honest labeling, and preservation of health and prevention of deception are sound purposes for which the Agency should be given every necessary tool, but we respectfully submit that the review of confidential financial and research information has no bearing on quality of product, safety, or marketing practices.

The Congress of the United States must ever be vigilant lest is readily accede to unnecessary requests for administrative power expansion. The subject bill is not needed. It is not desirable. This enactment would not be in the public interest. We urge that the unwarranted powers sought by proposed sections 201 and 202 be deleted and that the agency not be given powers and authority to concern itself with matters wholely apart from the statutory objectives.

Our association and its members will be happy for the opportunity of providing you or your committee with any additional information if this would be helpful.

Yours very truly,

HENRY A. BUCKLIN, *Executive Secretary.*

MAYONNAISE & SALAD DRESSING MANUFACTURERS' ASSOCIATION, INC.,
Chicago, Ill., May 29, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The Mayonnaise & Salad Dressing Manufacturers' Association is a trade association of independent manufacturers of dressing products. Its members are vitally concerned because of a measure now before your committee—namely, H.R. 11581. After careful study, the board of directors of this association have adopted a resolution opposing the proposed amendment

to the Federal Food, Drug and Cosmetic Act, expanding factory inspection powers. We wish to set forth for your consideration our objections to the proposed expansion of factory inspection powers.

Under the newly proposed provisions of H.R. 11581, Food and Drug Administration inspectors, whose responsibilities and duties have heretofore been limited to protecting the public as to food and drug products, would be given the right to probe into financial and personnel records, and in addition, have access without reservation into confidential records relating to research and product development. These powers are so remotely connected with the statutory objectives and with the preservation of public interest that they cannot be defended as essential, or even reasonable to the protection of the public interest.

We believe that questions concerning the wholesomeness, honest labelling, preservation of health and the prevention of deception are sound purposes, for which this agency should be given every necessary tool. But we submit that the review of confidential financial and research information has no bearing on protection of quality, safety or marketing practices.

We believe the Congress of the United States must be vigilant lest it readily accede to unnecessary requests for administrative expansion of power. The subject bill, in our opinion, is definitely not needed. Moreover, it is not even desirable. The results would not be in the public interest. We urge that the unwarranted powers set forth under proposed sections 201 and 202 be deleted, and that the agency not be given powers or authority over matters completely apart from the statutory objectives.

If it would be helpful, our association and its members will be glad to provide you and your committee with additional information.

Sincerely,

WENDELL W. BISHOP,
President.

SEEMAN BROS., INC.,
New York, N.Y., May 31, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR REPRESENTATIVE HARRIS: I wish to express my opposition to the enactment in its present form of H.R. 11581, now before the House Committee on Interstate and Foreign Commerce. I would find the bill more acceptable if certain reasonable changes were made in it.

The bill is obviously a response to unique facts disclosed during investigation of the drug industry by Senator Kefauver's Antitrust Subcommittee. The food industry was not involved in that investigation. The bill gives inspectors under the Federal Food, Drug, and Cosmetic Act unreasonable and excessively broad powers to inspect factories. These powers are clearly unrelated to, and go far beyond, those purposes of the act aimed at preventing adulteration and misbranding in the manufacture of food.

The food drug industries are different and have different problems and characteristics. Therefore, legislation intended for the drug industry should not include the food industry automatically and except for the most compelling reasons.

Accordingly, I strongly urge you to oppose the application of the factory inspection provisions of H.R. 11581 to the food industry. This can best be accomplished at this time by supporting a severance of the factory inspection provisions of the act so that the food and drug industries will be treated separately and in accordance with their own distinctive problems.

Sincerely,

WALKER R. GOODRICH,
Vice President, Personnel.

NATIONAL PRESERVERS ASSOCIATION,
Chicago, Ill., May 31, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The National Preservers Association, a trade association comprised of the manufacturers of jams, jellies, preserves, and

fruit spreads, respectfully wishes to express its opinion with respect to the proposed broadening of factory inspection powers in the Federal Food, Drug and Cosmetic Act. A review of our membership indicates that the preserve industry has real misgivings concerning the true need for the expanded powers proposed by H.R. 11581.

These misgivings do not refer to the general regulatory principles of the FDA, nor to the manner in which these principles are applied. As a matter of fact, NPA, representing one of the more important segments of the food industry, has felt that such principles generally have been fairly and reasonably administered to the distinct well-being of the general public. Our association has consistently approved and applauded the objectives of the Federal and State food, drug and cosmetic laws. However, the current proposal to provide FDA inspectors with power to examine financial and personnel records and files seems to have scant reference to the intention and spirit of such legislation; surely no excuse can be set forth for an examination of records on research and development of product.

To be more specific, the past record of the food industry in general, and the preserve industry, in particular, indicates that the present provisions of the Food, Drug and Cosmetic Act are more than adequate. Increased factory inspection powers would merely create additional and unnecessary requirements that would needlessly consume time and would be expensive to the preserve industry, and therefore to the consumer.

It has been regular practice among preservers to make available all information needed by the FDA on a cooperative and willing basis wherever there has been any question regarding the wholesomeness or sanitation of product. Extended authority will very likely result in the need for the preserve manufacturers to incur additional costs to operate in order to provide information asked for, but of very questionable value insofar as the consumer is concerned either from the point of view of health, sanitation or deception. There is no question that H.R. 11581 would open up for review confidential financial and product information having no bearing on product quality, safety or possible deceptive practices.

There has been no demonstrated need for additional authority by which a more effective enforcement of the Federal Food, Drug and Cosmetic Act would be obtained, and which is not available to it under the present authority. If any such need can be demonstrated for extension of the authority in specific areas pertinent to the purpose of the act, legislation restricted to such specific areas of inquiry can be proposed for study. The National Preservers Association feels that experience, not only in its own industry but in the food industry in general, has not been such as would justify the sweeping factory inspection powers now sought which include within its scope power to demand information regarding products and personnel rightfully considered confidential.

In view of the above policy, the NPA board of directors has recently passed the following resolution:

"*Resolved*, That the National Preservers Association oppose any proposed amendment to the Federal Food, Drug and Cosmetic Act which would extend the factory inspection powers under the act beyond the powers as presently provided in the factory inspection provisions and the food additives amendment, of the Federal Food, Drug and Cosmetic Act; and that the officers and staff are authorized to do everything deemed reasonably necessary, in their judgment, to oppose any legislation which would expand this power and, to this end, cooperate and coordinate its actions with other affected industry groups."

We, therefore, wish to place ourselves on record with your committee, urging that sections 201 and 202 be deleted from H.R. 11581 prior to submission of this bill to the House of Representatives for a vote.

Thank you for your kind attention to this matter. We shall be happy to provide additional information in support of the above points if you so desire.

Sincerely,

J. M. MAJOR, Jr., *President.*

VINELAND, N.J., *May 31, 1962.*

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

MY DEAR CONGRESSMAN HARRIS: May I express my opposition to the enactment of H.R. 11581 in its present form, now before the House Committee on Inter-

state and Foreign Commerce. The bill would be more acceptable if certain reasonable changes were made in it.

The bill appears to derive from certain facts disclosed during investigation of the drug industry by Senator Kefauver's Antitrust Subcommittee. The food industry was not involved in that investigation. The bill gives inspectors under the Federal Food, Drug, and Cosmetic Act unreasonable and excessively broad powers to inspect factories. These powers are clearly unrelated to, and go far beyond, those purposes of the act aimed at preventing adulteration and misbranding in the manufacture of food.

The food and drug industries differ. They have different problems and characteristics. Legislation intended for the drug industry cannot be applied automatically to the food industry.

May I strongly urge you to oppose the application of the factory inspection provisions of H.R. 11581 to the food industry. I suggest that this can best be accomplished at this time by supporting a severance of the factory inspection provisions of the act so that the food and drug industries will be treated separately and in accordance with their own distinctive problems.

Very truly yours,

FRANCIS V. ANDERSON.

STATEMENT OF HELENE CURTIS INDUSTRIES, INC., REGARDING H.R. 11582, THE COSMETIC CONTROL ACT

This statement is submitted by Helene Curtis Industries, Inc., in opposition to H.R. 11582.

Helene Curtis Industries, Inc., is one of the largest toiletries manufacturers in the United States and the leading U.S. company in the hair care field. The provisions of H.R. 11582 will vitally affect the operations of Helene Curtis and for this reason this statement of opposition is respectfully submitted to the Committee on Interstate and Foreign Commerce.

Helene Curtis objects to the proposed bill on two general grounds. The proposed changes are unnecessary for the welfare of the country and the proposed changes are unnecessarily economically burdensome to the companies concerned.

The great majority of toiletries and cosmetics sold within the United States are marketed by companies of the size, stability, and responsibility of Helene Curtis. These are companies that have shown over a period of many years that their products are tested carefully for safety and efficacy. The control procedures of these companies have been carefully and systematically set up to insure the safety of the public in its use of these products. Millions of dollars are spent each year by these companies that assume a moral responsibility that far transcends the legal responsibilities imposed on them.

The record of safety and care in this industry is one of which the industry can be proud. This is all the more impressive when it is considered that millions, perhaps billions, of these products have been sold and are in use at the present time. The sporadic instance of a product reaching the market that is not safe is a rare exception to this statement. It is certainly not normal or customary. Unfortunately the bad product will receive all of the publicity and the millions of safe uses are forgoten.

We respectfully submit that the occasional bad product that may reach the public can, first, be adequately controlled under the present law and, second, does not justify the greatly increased expense of operation that the new bill would place upon manufacturers.

Since so much will depend upon the regulations and rulings that will be issued under the proposed bill, we cannot know for sure exactly how the proposed procedures will operate. We can only assume that the procedures will be roughly comparable to those adopted for the introduction of a drug under the present law. Experience has shown that the obtaining of a new drug approval constitutes a major expense and a major undertaking of the company seeking such approval. We can assume that substantially the same will be true with respect to obtaining approval of a new cosmetic. As previously indicated, we believe that present testing by the companies in the toiletries field is careful and complete. To add to the problems inherent in the introduction of a new product those requirements that a Government agency would consider to be required is unnecessary. The law as it now stands gives adequate remedies and power to protect the public whenever and wherever this is required.

In addition to what has been stated above, the proposed amendment revoking the exemption of coal tar colors deserves a statement to itself. This one aspect of the bill will probably ruin an entire segment of the beauty industry. Almost the entire hair-coloring field utilizes coal tar colors which have had special dispensation under the present law, which dispensation has been amply justified over the years. If this is revoked, all of this business will be done away with, at a loss of millions of dollars to the manufacturers and at the cost of depriving those women of the world who desire to color their hair of the opportunity to do so. Again, this proposed revocation is being set forth in the face of a record showing successful and safe use of these coal tar colors over millions of applications and over many years. The revocation of the exemption for coal tar colors is unnecessary and uncalled for at this time.

For the reasons set forth in this statement, we respectfully submit that H.R. 11582 should not be favorably reported out of this committee.

STATEMENT OF EDWARD J. MASTERS ON BEHALF OF HELENA RUBINSTEIN, INC., RE H.R. 11582

I am Edward J. Masters, director of product research and development of Helena Rubinstein, Inc. I have been employed in that capacity since 1948. This company, or its predecessor in interest, has been engaged in the manufacture, distribution, and sale of cosmetics and related products in the United States for almost 50 years. I hold a B.S. degree and a M. Ch. E. (chemical engineering) degree from the City College of the City of New York and a Ph. D. degree from Columbia University in the field of organic chemistry. Prior to joining the Rubinstein organization I was a research chemist and factory manager with Evans Associates, cosmetic manufacturers and consultants.

As director of product research and development of Helena Rubinstein, Inc., I am responsible for the technical development of each and every product.

This statement is limited to proposed title I of H.R. 11582 concerning the premarketing clearance of cosmetics for safety. Since I am not a lawyer, I am not in a position to suggest specific modifications to the sections proposed under this title. We understand that the Toilet Goods Association will appear and recommend specific modifications to clarify and improve certain provisions of H.R. 11582. My submission involves its provisions from a technical and scenitific point of view, with specific background data covering the practices and procedures of the company with respect to the premarketing testing of its products and the safety record over the past 8 years of products distributed by Helena Rubinstein, Inc. I trust that these background data will be of some value to the committee.

At the outset, I should like to make it clear that Helena Rubinstein, Inc., is in favor of appropriate pretesting of cosmetics prior to their release to the consumer. We consider such pretesting not only our moral responsibility, but also a practical business necessity. At the present time the provisions of the Food, Drug, and Cosmetic Act define cosmetics as articles which are intended to be applied to the human body for cleasing, beautifying, promoting attractiveness, or altering the appearance. Any cosmetic product which is intended to affect the structure or function of the skin is considered a drug. Thus some preparations, having a duality of function, may be both drugs and cosmetics. Deodorants and bleach creams, for example, have been and are classified both as drugs and cosmetics, or in our terminology, "cosmetic drugs." These cosmetic drugs, designed for a physiological effect upon the skin of the person using them, are subject to all the drug provisions of the present law, including the provisions relative to new drugs. Helena Rubinstein, Inc., distributes both cosmetics and cosmetic drugs.

We, at Helena Rubinstein, Inc., have no objection to premarketing testing of new cosmetics provided that a new cosmetic can be defined in understandable language and provided, further, that said testing does not impose a completely unnecessary an unwarranted burden upon the cosmetic manufacturer. However, in reviewing the definition of a new cosmetic under proposed section 605(a), I have found it to be so vague and indefinite that I cannot interpret practically what is and what is not "new." In fact I cannot determine whether our old products would be in the category of products used for "a material extent or for

a material time." Section 605(a)(2) would appear to require the filing of a new cosmetic application (the equivalent of that required for a new drug) if a manufacturer wished to incorporate any supplemental ingredient, even though such ingredient is fully recognized as safe but is merely new to the existing time-tested formula. And even a minor improvement of an existing formula would subject the product to the new cosmetic sections of the act. Last year, for example, our product line alone was subjected to 140 minor or major changes—any or all of which might subject these products to the proposed new cosmetic provisions. Every modification of such nature might entail the filing of a complete new cosmetic application involving not only a substantial expenditure of time and money, but also the compounded administrative work of those who must process these applications. We have found that the processing of a new drug application covering our cosmetic drug products costs a minimum of $25,000 and 3 years in time.

I should also like to comment concerning section 605(d)(2), the section dealing with the presumptive carcinogenic potential of cosmetics. For instance, the use of the phrase "any reasonably forseeable use" is vague and capable of varied interpretation. The phrase in section 605(d)(2)(B) "or after other relevant exposure of man or animal to such cosmetic" opens the door to the imposition of requirements which are utterly unrelated to the prospective use of the cosmetic. It is known that persistent and chronic irritation from any source can produce cancer after a long period of insult. Pure water itself has been reported to have produced cancer after repeated injection into the skins of susceptible animals. And one cannot consider water a carcinogenic agent. Therefore the protocol for testing a cosmetic intended for topical application for potential carcinogenicity should be limited to topical application in a dosage range appropriate to the intended use of the product.

Apart from these comments, this committee may be interested in the procedures employed by Helena Rubinstein, Inc., in the testing of its products. A typical evaluation of a new product may involve testing for basic toxicity, primary irritation and sensitivity. In the normal order of testing, the basic toxicity and the primary irritation characteristics are first established. Allergic sensitivity tests on human beings then follow along with use tests. The company maintains animal facilities and a histological and histochemical laboratory to perform both safety and other studies. Basis toxicity and primary irritation tests are run on animals of different species (mice, rats, guinea pigs, rabbits). If the product is to be used in the vicinity of the eye (shampoos, eye cosmetics), then a test is run on rabbits (Draize rabbit eye test) to establish whether any injury occurs on instillation into the eye. If all the above tests indicate the product is satisfactory, then patch tests are run on a panel of human beings by our consultant dermatologist to establish whether the product is a sensitizer. Physicians then run clinical use tests to establish further its safety and acceptability.

If the new ingredient or product falls in the category of a new drug, all the safety test data along with formula, labeling, control, and manufacturing procedures are submitted in the form of a new drug application to the Federal Food and Drug Administration. A number of products in our line fall into this category.

In December 1959, at a symposium on cosmetic allergy presented before the Section on Allergy of the Medical Society of the County of Kings and the Academy of Medicine of Brooklyn, subsequently published in the New York State Journal of Medicine, volume 60, No. 12, June 15, 1960, a copy of which is annexed hereto,[1] I discussed allergies to cosmetic products. In this paper, I incorporated a summary covering "a major cosmetic company's experience on complaints of reactions to its products" during the period from July 1, 1954, to August 31, 1959. The major cosmetic company to which I referred was Helena Rubinstein, Inc.

The following tabulation sets forth our cumulative experience for the period July 1, 1954, through April 30, 1962. Here, too, the number of reactions given include all complaints of alleged adverse reactions to the use of a specific product.

[1] The symposium may be found in the files of the committee.

Reactions compared with unit sales for period July 1, 1954–Apr. 30, 1962

Categories	Reactions	Units sold	Reactions per 1,000,000
1. Depilatories	164	4,659,338	34.9
2. Special cleaners	81	4,743,262	17.2
3. Permanent wave lotions	18	1,132,075	16.4
4. Permanent hair rinses	75	7,932,423	9.5
5. Hormone creams and lotions	45	5,059,983	8.8
6. Medicated creams and lotions	40	5,016,722	8.0
7. Lotions	84	16,502,396	5.1
8. Eye products	91	18,133,573	5.0
9. Creams	28	6,015,718	4.7
10. Sun tan lotions and oils	3	732,102	4.3
11. Deodorants	17	5,550,995	3.0
12. Hair dyes	10	3,554,047	2.8
13. Hair rinses	13	4,898,957	2.7
14. Miscellaneous hair treatment products	19	7,470,058	2.5
15. Shampoos	35	17,454,740	2.0
16. Makeup	21	14,419,401	1.5
17. Face and body powder	6	11,555,393	.5
18. Colognes and perfumes	8	21,890,882	.4
19. Lipsticks	5	19,654,145	.3
20. Nail polish	0	681,177	0
Total	763	177,057,397	4.3

NOTE.—A total of 763 reactions in 177,057,397 units sold is good testimony to the general safety of cosmetic products.

STATEMENT OF MISS BETTE JACKSON ON BEHALF OF COSMETIC CAREER WOMEN, INC., ON H.R. 11582

My name is Bette Jackson. I am product publicity manager of Shulton, Inc., manufacturers of cosmetics, a large part of whose business is in products for men. I am here representing Cosmetic Career Women, Inc., an organization of executive women engaged in the cosmetic and toilet preparations industry, with a membership of approximately 200.

We requested an appearance before your honorable committee because we believe that H R. 11582 is poorly calculated to accomplish its ostensible purpose; namely, to protect the men and women of this country from harmful products. The fact of the matter is, we are by no means convinced that the perfumes, cosmetics, and other toilet preparations sold by the manufacturers in this country have any capacity for harm to anyone other than to perhaps some person who is allergic. Even for the allergic person, the possibility of harm from strawberries, shellfish, and many other common and familiar products, is far greater than it is from cosmetics.

Our organization believes in safe products and it has no objection to the principle of this bill which is ostensibly designed to require really new products to be tested before they are sold, but we are convinced that the methods attempted by the drafters of this proposed legislation show less sign of consumer protection than an effort to place unduly restrictive controls, far stronger than those in effect on foods and drugs, on an entire industry, which contributes greatly to the American economy, which employs many thousands of people and which pays retail excise taxes to the Government annually of nearly $150 million, in addition to the other taxes which any prosperous American industry pays.

We are particularly interested in this measure because women are the principal users of the products of the industry and the principal buyers, even of those products which are used by the male population. We know from personal experience that the use of cosmetics and other toilet preparations contributes not only to health, to cleanliness, to our appearance but also greatly to our morale. The morale factor is very important. We would point out, for example, that during World War II, the British Government believed it could abolish the manufacture of cosmetics in England and took steps to do so. The result was an immediate and sharp decline in the morale of the many patriotic and brave women working in the war plants. They felt they did not look right and accordingly, did not feel right about their jobs, about their positions in society or about their Government. Further than that, during the very short time before the British Government found its mistake, a black market in cosmetics made in garages, stables, apartments, and other places, menaced the

welfare of the women of that country. Also, among our own members, there are women who are sent out by their companies to lecture to inmates of prisons and patients in mental hospitals on the morale-boosting effects of cosmetics, and Cosmetic Career Women annually contributes money to assist in good-grooming classes for blind women in New York City.

Insofar as the proposed legislation which we are discussing is concerned, undoubtedly it would deprive women of certain products which they are accustomed to use and which we believe they have every right to use. For example, hair-coloring materials which now account for about $100 million at retail annually and for some $10 million in excise taxes to the Treasury, would no longer be available to those who desire them. We know, of course, that some people do not like women to color their hair but we also know that a large and growing percentage of American women desire to do so and we can see nothing wrong with the custom if women want to indulge in it. Incidentally, many women undoubtedly need to indulge in hair coloring to save their jobs and perhaps even to hold their husbands.

In addition, we resent any legislation in the United States which places the control of any industry, and particularly our industry, at the whim of a governmental department which could act under this proposed legislation in a completely arbitrary manner, and deprive us of products which we desire, and prevent a manufacturer from manufacturing the products which he desires to make. This, gentlemen, we feel to be an open end bill, giving to the Secretary of Health, Education, and Welfare and accordingly, to the Food and Drug Administration complete authority over every product we make. The sections of the bill designed to bring about the testing of what the bill calls new cosmetics, and the definition of "new cosmetic" in the measure are so imperfect, that if the Secretary desired, and we can foresee that at some time he could so desire, he could stop the sale of cold cream, invented by Galen, the Greek physician, about 200 A.D., nearly 1,800 years ago, if he should find in his wisdom that the product had not been found to be safe and he could require that manufacturers using the Galen formula (and many manufacturers are using somewhat the same formula today), spend many thousands of dollars proving something to be safe that had been in use for 1,800 years by millions of women without any history of damage This, we respectfully submit, is far too much authority to give to any bureaucrat.

One of the leaders in our industry some years ago, in a magazine interview, stated "This industry is one of ideas and ingenuity and what we are really selling is hope." This may seem at first glance to be a slur against the industry, but we submit that if the women of this country should lose the opportunity of continuing to look young and beautiful to their menfolk, we would be in a sad state indeed Further than that, the industry has over the years realized that hope to which I previously referred. The products of the industry have brought beauty, health, and a sense of well-being to practically every woman in the country and to a great many men as well, who have found that the use of such things as deodorants, aftershave lotion, and similar products have made it easier for them to face the world when they go out to their places of business each morning Not only has the hope been realized, but the completely indefensible claims of damage to the public from the use of these so-called untested products do not agree with the facts which every careful competitive manufacturer develops from day to day. The number of claims of harm caused by cosmetics are so trifling as to be negligible. In fact, we are advised that in the nearly 25 years since the enactment of the Food, Drug, and Cosmetic Act, slightly over 200 cases have been brought by the Food and Drug Administration against cosmetic products were other industries covered by the same law have been cited far more often.

We realize that it is the tendency of Government bureaus to seek more and more authority—that is history. This measure, if it should unfortunately be passed, would place a tremendous burden upon the industry. It would do nothing but increase materially the price of safe cosmetics to every American woman. It would do nothing but discourage those ideas and that ingenuity to which I have already referred because the small fellow with a bright idea for a new cosmetic could never get into business under this measure but would have to do, hat in hand, to a big manufacturer, hoping to sell the idea for a few dollars and a job. We do not believe that this committee nor the Congress itself desires to jeopardize the small businessman or the ingenuity and ideas which have made the industrial picture of America so great.

Others are more competent than we to discuss the technical aspects of this bill and we shall leave that to them, but we urge that this committee send the measure back to its drafters in the Food and Drug Administration and in the Department of Health, Education, and Welfare with the suggestion that they draft a more perfect measure to accomplish a laudable principle and that, since this is such a tremendous job, every phase of it be discussed with industry before another bill is brought before your committee next year.

Thank you for allowing me to appear.

STATEMENT FOR CONSUMERS' RESEARCH, INC., BY F. J. SCHLINK, PRESIDENT AND TECHNICAL DIRECTOR, CONCERNING H.R. 11582, SECTION 302

This amendment, which would relax present anticancer clauses with respect to feed for animals, is objectionable, and dangerous in many respects.

The feeding to food animals of substances which are known to be cancer-causing is so obviously a risky business that it should not be tolerated at all except perhaps for the most compelling reasons, such as imminent famine or the emergency of nuclear warfare. The proposed legislation, however, opens the floodgates without any regard to the needs for the proposed additives.

Subsection 302(b) goes to the absurd length of permitting potentially dangerous food components to be used for no other purpose than to impart color to feeds for animals. Are we to increase our possible exposure to cancer, by any unknown amount, even if small, in order that cattle and swine feeds can be made in attractive hues, for appearance, or to distinguish one type of feed from another, for farmers' and feed dealers convenience?

If the section were adopted, animals raised for food production would be given less protection against carcinogenic materials than would all other animals fed by man, such as beasts of burden, domestic pets, and the denizens of zoos.

A "finding" by the Secretary that certain conditions of use and feeding are "reasonably certain to be followed in practice" will be no protection to the thousands, ultimately millions, of consumers who will eat the flesh and drink the milk of those animals which represent the unavoidable deviations from the "reasonably certain" feeding procedures.

Under this section's provisions, the health of every consumer will depend on the willingness and ability of countless farmers and farmhands to read, understand, and carry out complicated, precise directions for mixing feeds and distributing them to animals. There are no literacy tests for farmworkers, and it is traditional that directions are not read and followed even by people who read well.

The language of the bill calls for the Secretary to find "(ii) that no residue of the additive will be found * * * in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal." However, no provision is made for dealing with the situation if such residues are found despite the Secretary's "finding" that they will not be. A variation is conditions of feeding, climate, or animal health could readily invalidate findings made under the necessarily used laboratory conditions.

Furthermore, the conditions under which the Secretary's findings as to absence of residues are to be made are not clearly stated. Perhaps unintentionally, the proposed amendment is worded so that the phrase, "under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice" (p. 26, lines 20–22) does not apply to clause (ii) beginning on line 24. [There is analogous wording in subsection (b).] The net result of this wording is that the Secretary must determine in advance that no residue will be found, without any statement of the conditions of use or feeding under which such finding is to be made. This is not a valid requirement, since no finding could ever be reached that the edible animal products will never contain a residue of a carcinogenic substance.

However, the most important objections to section 302 are (a) that it does not provide for a showing of compelling need before use of an additive which has been shown to be carcinogenic, (b) that it permits use of carcinogenic color additives for which surely there has not been and never is a compelling need in animal feed, and (c) that it makes no provision for dealing with the situation in which a residue is detected in human food despite a prior finding that it would not be.

We believe that section 302 in its entirety should be deleted from H.R. 11582.

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STATEMENT FOR CONSUMERS' RESEARCH, INC., BY F. J. SCHLINK, PRESIDENT AND TECHNICAL DIRECTOR, CONCERNING H.R. 11582, SECTION 303

We are in agreement with the general intent beginning of this section, up to line 16, page 28. We are concerned, however, about the implications of the phrase, "if such prior sanction or approval had been made public" (lines 16-17) and we are disturbed that the amendment appears to provide a special method of treatment for prior sanctions or approvals which were not made public.

We believe that all sanctions or approvals should be publicly granted or not granted at all, that all such actions as have been taken secretly in the past should be required to be made public now, or else should be rescinded and have no further force and effect, and that any future actions with respect to prior sanctions or approvals (for example, as provided in the proposed amendment under discussion) should be taken only with full public notice and opportunity for interested persons to be heard, regardless of whether any earlier related action was public or secret.

TESTIMONY OF MR. JOHN F. MALO ON H.R. 11582

My name is John F. Malo. I reside at 2455 South Jackson Street, Denver, Colo. I am vice president and one of the owners of Intermountain Elevator Co. at Denver, Longmont, and Hudson, Colo., which company manufactures cattle feed supplements for sale in large bulk quantities to cattle feeders. The cattle feeding business is a major industry in this country, and cattle feeding is a highly developed science, being particularly important to the economy of the State of Colorado.

One of the developments has been the increasing use of antibiotics, vitamins, minerals, diethylstilbestrol and other ingredients designed to promote growth and increase feed efficiency.

I am appearing here in support of the proposed section 302 of the Harris bill. The reason is that under the present law as interpreted by the Food and Drug Administration I cannot manufacture my feed supplements in an efficient way and I do not receive equal treatment to that of some of my competitors. The proposed section 302, which is sponsored by the Food and Drug Administration, and supported by the President, will give to the FDA the authority needed to bring about fair and equal treatment and to permit greater efficiency.

Let me explain why. We use a substance called diethylstilbestrol (DES) in our feed supplements to promote growth of the cattle. Prior to 1958 the FDA had issued hundreds of new drug applications or supplements permitting the use of DES in a variety of formulas and in varying combinations with other ingredients. We, in fact, have several authorizations to use DES in our formulas.

In 1958, after the passage of the food additives amendment which included the "Delaney clause," the FDA refused to issue any new supplements for the use of DES or to permit any amendments or supplements to existing authorizations such as ours. They took this position, I understand, because apparently DES was a carcinogen.

However, based on all available data we have, and here the Food and Drug Administration agrees, DES will not cause cancer in beef cattle, nor will any harmful residues remain in the edible portion of the treated animal.

Indeed, since the drug was not harmful to cattle, the FDA permitted the existing authorizations to remain in effect after 1958.

A basic unfairness has resulted. A newcomer cannot obtain an authorization to use DES. Existing holders of authorizations, such as our company, are not permitted to amend or supplement their authorization. We recently desired, at the request of one of our large customers, to combine DES and aureomycin into one cattle supplement, a combination which involved no dangers to health. The FDA would not approve this change in our authorization. The sole net result of the Administrator's action is simply to drive our customers to our competitors who by sheer chance happened to hold a prior issued authorization for the right combination. The cattle feeder desires, for reasons of economy of time and money, to have both ingredients in the feed pellet. He doesn't care which supplier he uses if he is able to obtain the desired combination. Thus all—and I wish to repeat—all the present law does is to discriminate as between manufacturers of these feed supplements. There is absolutely no element of public health involved whatsoever. Cattle are still being fed DES in

combination with other ingredients, and people are still eating the beef. But some manufacturers are favored over others. This, I am sure, was not the intended congressional purpose.

To point up the ridiculousness of the present situation, let me give you two further illustrations. Though we are not permitted to mix DES with new ingredients, the feeder himself can. Thus, I can furnish him a feed pellet with DES in it; he can obtain some other component and mix it together in his mixers. It is more expensive for him; it is less efficient; it may even be less safe. But he can do it and we can't. I have attached to this testimony a letter I received from one of my good customers, Mr. David C. Wilhelm, of Rocky Ford, Colo., pointing out how silly this seems to the cattle feeders and how they will simply have to switch their purchases to another manufacturer. I am also attaching a letter from Kenneth Monfort, a large cattle feeder in Greeley, Colo., attesting to the need to combine DES and other ingredients for maximum efficiency. I have already lost business on this account and I expect to lose more unless this situation is remedied immediately.

Another illustration further highlights the need for change. We recently installed brandnew facilities at Longmont, Colo., brandnew equipment, subject to careful controls, and we certainly are able to manufacture these supplements as safely, if not more safely than many of our competitors. Yet we are forbidden to use these new, modern facilities, because some of our existing authorizations specify a different plant location, and we can't even change the location.

Obviously our company is vitally concerned with the health of our Nation; we don't desire to introduce into cattle feed any ingredient which may possibly jeopardize the health of man or animals. But DES used in the combinations we propose cannot, in any way, be harmful or dangerous.

As I said before, the proposed section 302, which is sponsored by the FDA, will give the FDA the express authority to issue new drug applications or supplements where it can be shown that the drug would do no harm to the animal, and where, under prescribed conditions of use, no residue of the carcinogen remains in the edible tissue of the treated animal. In short, where it can be shown that the beef would be absolutely safe for human consumption, then the Secretary could issue the authority. This would clearly cover our situation and is, we believe, a sound and fair position. The emphasis will be again on safety to the public, where it belongs, and not on favoritism as between competitors.

I appreciate this opportunity to come before you and briefly describe what has happened to us in Colorado, because I know our case is typical of other feed manufacturers. I am confident that as you hear these examples of how the present law is being applied, you will see the need for the proposed legislation.

WILHELM-MANCINI FEED LOTS,
Rocky Ford, Colo., June 19, 1962.

Mr. JOHN F. MALO,
Vice President, Intermountain Elevator Co.,
Denver, Colo.

DEAR MR. MALO: You have manufactured our feed for our cattle feeding operation now for 5 years, and we have always been satisfied with your treatment of our demands. We finish approximately 20,000 cattle per year, and I am sure the business is a benefit for you also.

However, we are now interested in having you incorporate both stilbestrol and either terramycin or aureomycin into our protein supplement. We are able to buy the stilbestrol in our protein now from you, but you have told us that we must buy our aureomycin in a product called Aurofac 40 and add that to our feed ourselves. We realize we can do this, but this is most cost consuming because of the costs of storage, mixing, and feeding. We would like you to incorporate this additive rather than us, and you say you are prohibited by law. We don't understand this nonsense. This seems unfair, unfounded, and without reason. Whatever the reasoning is, however, we may be forced to switch our protein purchases to another manufacturer, who has the license to mix the above ingredients, because, as I know you understand, we must feed as efficiently as possible.

Please see if there is any way to remedy this matter and inform us immediately.

Yours very truly,

DAVID C. WILHELM, *Managing Partner.*

JUNE 18, 1962.

Mr. JACK MALO,
Intermountain Elevator Co.,
Denver, Colo.

DEAR JACK: This letter is in answer to our telephone discussion of today regarding your attempt to get set up to supply us with our formula food supplement. As you know, I believe it extremely silly that you cannot supply us with the formula of feed that we desire while your competitors in the area can and do. I believe that in order to assure our competitive position in the livestock production business, we must be able to take advantage of competitive bids on our supplementary feed mix. We can get these competitive bids only if it is possible for every competent feed supplier in the area to bid on our mix according to our specifications.

As you know, we feed and market about 70,000 heads of fed cattle per year. Our county is the largest single cattle feeding county in the country. A sizable percentage of the choice and prime beef consumed both on the east coast and the west coast comes from the feedlots in northern Colorado. We, at our feed lot, and other cattle feeders in the area have tested different rations for years. Colorado State University, along with other land-grant universities and colleges have conducted far reaching and extensive testing of feeding rations and additives in order to make cattle feeding a truly immense and economical part of the farming picture. I think it worth noting here that the cattle feeding industry is a part of agriculture that is wholly self-sufficient and extremely healthy. This has been accomplished only by the use of all available technology in the field. The cattle feeding industry not only is tremendously healthy, but, in fact, is growing so rapidly that it is today showing signs of eventually being able to devour our present burdensome supply of feed grains. These facts are only presented to you as background material for the request that follows.

As you know, our tests as well as university tests have proven to us that we should feed both stilbestrol and an antibiotic to our cattle on feed. I believe the majority of the other feeders in the area need and want to do the same thing. At the present time there is only one mill with significant capacity that is licensed to produce such a feed. To me, this is completely ridiculous and anything that you can do to alleviate this situation will not only be appreciated, but will be a service to our area and the cattle feeding industry throughout the country.

Sincerely,

KENNETH MONFORT, *Vice President.*

STATEMENT OF THE NATIONAL HAIRDRESSERS & COSMETOLOGISTS ASSOCIATION IN OPPOSITION TO SECTION 103 OF H.R. 11582 SUBMITTED BY ROBERT A. COLLIER

This statement is submitted by the National Hairdressers & Cosmetologists Association, Inc., in opposition to section 103 of H.R. 11582, the Cosmetics and Therapeutic Devices Amendments of 1962. The association represents more than 65,000 beauty salon owners and operators with a total employment of more than 150,000 trained and licensed cosmetologists.

Section 103 of H.R. 11582 would repeal the special exemptions of hair dyes contained in the Federal Food, Drug, and Cosmetics Act. The effect of this proposed repeal would be to subject the color additives used in hair dyes to the listing and certification requirements of section 706 of the act.

Under present law, coal-tar dyes are not subject to the statutory provision relating to cosmetics if the label bears the following legend conspicuously displayed thereon:

"Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

The present statute also requires that the label bear adequate directions for such preliminary testing.

Only coal-tar dyes have proven effective in the manufacturing of hair dye products. The many years of experience with the hair colorings currently in use, especially those of the oxidation type, have demonstrated the safety of using these colorings when applied by professional cosmetologists. Moreover, the

continued use of these products has increased our understanding of their effects and has in turn led to the use of purer ingredients compounded to more exacting standards.

Any individual who reacts adversely to these hair colorings does so solely because of an individual allergy to the product. The percentage of the total population who have an allergic reaction to coal-tar hair colorings is now so low that many other products currently marketed show a higher incidence of allergic response. The very small percentage of allergic reactions can easily be prevented by the method which is prescribed by the statute—the application by the cosmetologist of a simple preliminary test.

It is, therefore, indeed difficult to understand what useful purpose this proposed change in the law would serve. If this legislation were enacted, it would, of course, have no effect on the increasing demand for hair dye products. It is a well-known fact that the only effective hair colorings are made from coal tar.

Clearly, in view of the increasing public demand for hair dyes, and the lack of any appreciable incidence of allergic reaction, coal-tar dyes will in any case continue to be used by the public. In the event effective hair colorings were banned from legal distribution, then the great demand would, in all likelihood, create a "black market" to be filled by those who are unqualified to produce these colorings under anything resembling safe standards. If, as is more likely the case, the Secretary of Health, Education, and Welfare were to certify some coal-tar dyes under section 706, there would nevertheless remain a percentage of users who would have an allergic reaction to the dye. Some allergic reactions will inevitably remain even though the product meets certification requirements. It is highly doubtful whether this percentage will be any less than it is under present conditions and under the present state of the law. However, those who will remain allergic to the hair dye will not receive the benefits of the present law which requires that the label contain directions for preliminary testing. By eliminating this requirement, section 103 of this bill will serve to remove an existing safeguard to the public health without substituting any workable or effective alternative.

The public interest in effective and safe hair colorings is indeed great, and the evidence shows that this interest is being served by professional cosmetologists under the safeguards contained in the existing law. If a need exists for subjecting coal-tar hair dyes to the scrutiny of the Food and Drug Administration, such need is not based upon the experiences of patrons of professional cosmetologists.

Hair colorings serve a social, personal, and economic need. Individuals, especially females, seek to maintain their youth. Of course, youthfulness cannot be recaptured, but its appearance can be, and hair colorings help achieve and fulfill this desire. Women need to look young for social, as well as personal, reasons. To many, this appearance is mandatory if they are to compete successfully in the job market, particularly when the tendency is to cast in the "junk pile" anyone who is over 40. Gray hair is one of the first outward indications of advancing age: its concealment fulfills an economic need of many people.

The near-perfect safety record which cosmetologists have attained in the use of coal-tar hair dyes to serve these needs is the result of the proper application of these products by trained experts. It can be assumed that the relatively few adverse reactions occur in the self-application of coal-tar hair dyes by inexperienced home users of these products. To enact legislation which will include all coal-tar dyes within its scope, regardless of whether self-applied or used under an expert cosmetologist's supervision, is to penalize the professional cosmetologist for a situation which he has not created and which occurs because his services were not solicited. Thus, if the exemption is to be repealed, there is no justification for including the use of coal-tar hair dyes by professional cosmetologists within the scope of the repeal. Unfortunately, section 103 as presently written does not make this vital distinction between home use and professional application.

In view of the very doubtful benefits which this bill would provide, the economic losses to hairdressers and beauty salon operators would be appreciable. Hair coloring has become one of the most popular and most profitable aspects of the cosmetologist's business. Approximately 36 percent of the services rendered to beauty salon patrons consists of hair coloring. Of those utilizing these services, 70 percent are in the older and middle age classifications, and 58 percent are in the middle and lower income brackets. The disrupting effect of the bill upon this source of revenue can easily be imagined.

The 500,000 cosmetologists in the United States are dependent upon the use of coal-tar dyes for a significant part of their income, and they have used these products with a remarkable degree of safety in coloring hair. To enact legislation which may well prohibit their operations in this field on its present basis is to injure an important segment of the American economy without any assurance of corresponding benefits to the populace as a whole.

As recently as 1960, in the color additives amendment, Congress explicitly exempted coal-tar hair dyes from the scope of that legislation. That amendment to the Food, Drug, and Cosmetic Act made extensive changes in authorizing the use of suitable color additives in accordance with regulations to be issued to the Secretary of Health, Education, and Welfare. After an exhaustive study specifically directed to color additives the exemption for coal-tar hair dyes was permitted to remain in the act. To now amend the law, through a bill designed primarily to require a premarketing showing of the safety of cosmetics and the safety of therapeutic devices, would be contrary to the interests of the public and to the interests of the cosmetology industry.

In conclusion, the association contends that the present law is more than adequately protecting the public health in the use of hair dyes. Not only would section 103 of H.R. 11582 cause unjustified substantial economic loss and hardship to hairdressers and beauty salon operators, but it would also result in unnecessary added expense in the operations of the Food and Drug Administration. Most significantly, it would provide no assurance that the interests of the public would be more effectively protected than under present law.

STATEMENT OF THE AMERICAN PAPER & PULP ASSOCIATION, BY ROBERT E. O'CONNOR, EXECUTIVE SECRETARY, WITH RESPECT TO H.R. 11582, THE COSMETICS AND THERAPEUTIC DEVICES AMENDMENTS OF 1962

This statement is submitted to the House Committee on Interstate and Foreign Commerce by the American Paper & Pulp Association, the overall national association of the pulp and paper industry, in lieu of making a personal appearance with respect to H.R. 11582, the Cosmetics and Therapeutic Devices Amendments of 1962.

Section 303 of the Cosmetics and Therapeutic Devices Amendments of 1962, H.R 11582, which is now before the Committee on Interstate and Foreign Commerce, would amend the prior sanction clause of the food additives amendment.

The section provides that the exemption afforded in clause (4) of section 201(s) of the Federal Food, Drug, and Cosmetic Act shall be inapplicable if the Secretary finds that there is substantial doubt as to the safety of such substances. Except in cases of imminent hazard to public health, the Secretary may take such action only in conformity with section 4 of the Administrative Procedure Act if such prior sanction or approval had been made public.

There was published in the Federal Register of March 1, 1960, a list of substances used in the manufacture of paper and paperboard for food packaging which are exempt from the law in accordance with prior sanctions or approvals granted prior to enactment of the food additives amendment.

All of these substances are of vital importance to the pulp and paper industry, and the status of any of them should not be changed without a public hearing to determine whether substantial doubt as to safety exists.

Under section 303 of H.R. 11582, the Secretary's action, even though in conformity with section 4 of the Administrative Procedure Act, would not afford an adversely affected person an opportunity for a public hearing on the issue of whether substantial doubt as to safety exists. Therefore, we request and urge that section 303 of the bill be amended to provide that in all cases within 30 days after the Secretary's notice of proposed action, any person adversely affected may file objections thereto and request and receive a public hearing thereon. In the event that the Secretary finds that there is an imminent hazard to public health, a public hearing shall be held within 30 days after such determination.

Our recommendation may be accomplished by inserting at line 21, page 28 (sec. 303), of H.R. 11582, before the period, a comma and the following: "*Provided further*, That, within thirty days after notice of such proposed action, or, when the Secretary finds that there is an imminent hazard to public health, within thirty days after such determination, any person adversely affected by such proposed action or actions may file objections thereto and request and receive a public hearing on such objections as provided in subsection (f) of section 409

of the Act with respect to food additive regulations and the right of judicial review as provided by subsection (g) of section 409 of this Act with respect to food additive regulations."

AFFIDAVIT SUBMITTED BY NORMAN M. FROIKIN, ASSISTANT SECRETARY OF GLO-RNZ, INC.

STATE OF OHIO,
County of Montgomery, ss:

Norman M. Froikin, being first duly sworn according to law deposes and states—

That he is an assistant secretary of Glo-Rnz, Inc., an Ohio corporation; and

That said corporation is engaged in the manufacture and distribution of hair coloring products; and

That Glo-Rnz hair coloring products have been manufactured, marketed, and distributed nationally in the United States of America for more than 30 years; and

That during said period, many hundreds of millions of applications of Glo-Rnz hair coloring products have been sold and applied to human hair in both professional beauty shops and directly by the consumer in home applications; and

That to the knowledge of this affiant, there is not a single known instance of serious damage or injury claimed or proved, attributable to the use of hair coloring products manufactured and distributed by this firm; and

That in 1943, the Glo-Rnz Distributing Co. caused its products to be tested and studied by Smyth Laboratories, of Philadelphia, Pa., for the purpose of determining the safety of its products for use and consumption on human hair; and

That the method of testing employed in that study was that proposed by Dr. Louis Schwartz, Director of the Division of Industrial Dermatoses of the U.S. Public Health Service, and a copy of the Smyth Laboratories report is marked "Exhibit A" attached hereto and made part hereof; and

That following said testing and study, said Smyth Laboratories, by Dr. Herman A. Shelanski and Henry Field Smyth, M.D., D.P.H., reported:

"In all of the subjects studied, not a single reaction was obtained on this initial application with any of the test substances in either series. Therefore, we may safely say that the substance is not a primary irritant."

"The patches on second application were allowed to remain in contact with the skin for a period of 48 hours, at the end of which time they were removed and the skin reactions noted. Forty-eight hours is deemed sufficient to bring out a sensitization reaction if one has become sensitized. No reactions were obtained on any of the subjects on the second application with any of the test substances. Thus the substances do not appear to be sensitizing agents.

"Since no reactions were obtained on the first application of any of these substances, we say that these substances are not primary irritants, and since no reactions were obtained on second application, it appears that the substances are not sensitizers. From the above evidence, it is our belief that these preparations are neither sensitizing agents nor primary irritants."

That this company has maintained products bodily injury and property damage insurance coverage for its products for many years, and that to the knowledge of this affiant, not a single substantial claim has ever been paid in behalf of this company, to any individual as a result of a claim for serious bodily injury; and

That for the period approximating 3 years from April 7, 1959, to May 22, 1962, a total of $10 was paid for losses by the insurance carrier for bodily injury losses as a result of claims submitted, which obviously was a nuisance claim, and reference is herewith made to the statement of Wallace E. Stauffer, agent for Insurance Co. of North America, the products liability carrier, in statement marked "Exhibit B" attached hereto and made part hereof; and

That this company has taken reasonable preliminary precautionary steps to assure that its products are safe for their intended end use; and

That by virtue of the hundreds of millions of applications of hair coloring consumed by humans of its products with complete safety, and by virtue further of the studies and tests conducted by a responsible and recognized clinic and laboratory under the direction of medical and pharmaceutical doctors, according to methods proposed by outstanding authorities and, in particular, a former Director of the Division of Industrial Dermatoses of the U.S. Public Health Service, this affiant states and submits—

(*a*) That the hair coloring pigments and dyestuffs used in the manufacture and sale of this company's hair coloring products are reasonably safe for use on human hair.

(*b*) That this company has acted in a reasonably prudent manner to investigate and establish the safety of its products, and has continuously ever since conducted itself in a reasonable and prudent manner to maintain the safety and effectiveness of its products.

Further affiant sayeth not.

NORMAN M. FROIKIN,
Assistant Secretary of Glo-Rnz, Inc.

Sworn to and subscribed before be this 3d day of July 1962 by the aforesaid Norman M. Froikin.

[SEAL] ——— ———, *Notary Public.*

Lifetime notary commission.

STATEMENT OF M. PIER CO. BY C. P. PROSSER ON H.R. 11582

We would like to oppose, vehemently, H.R. 11582—the Cosmetics and Therapeutics Devices Amendments of 1962 with special emphasis on section 103 which repeals the special hair dyes exemptions. Our reasons follow:

AS REGARDS THE BEAUTY SALON INDUSTRY

1. The Federal Food, Drug, and Cosmetic Act passed in 1938 provided that hair dyes should be exempt provided such products were labeled in accordance with section 601(a) requiring an appropriate patch test be applied before use of the product.

Once again, in 1955, the FDA confirmed the safety of hair dyes in a letter by Food and Drug Commissioner Larrick to Jacob Reck dated June 3, 1955.

Again, in 1960, Congress in the color additives amendments affirmed the exemptions for hair dye products due to the nature of their application, use, and labeling.

The entire hair dye industry, employing thousands of people and involving the investment of millions of dolars has been based on and has been operating under these exemptions in the law

2. Since 1938, due to the removal of impurities, hair dye products have improved immeasurably. It is estimated that over 15 million women currently and safely use and are pleased with today's hair dye products.

3. There are over 800,000 hairdressers currently employed in the Nation's beauty salons. It is estimated that between 33⅓ percent and 40 percent of their receipts is derived from the application of today's hair dyes. These hairdressers will face unemployment or vastly reduced income if the hair dyes exemptions are repealed. Needless to say, the 15 million women currently using hair dyes will also be highly displeased when deprived of hair coloring products.

4. Many companies such as ours would be forced out of business if the hair dyes exemptions are repealed with resulting unemployment and loss of invested capital. In addition, there would be greatly reduced income or failure for the hundreds of beauty supply dealers which supply beauty shops, and lost or appreciably reduced income for their employees.

5. There would obviously be loss of public purchasing power, and loss of taxes to the Government if the hair dyes exemptions are repealed. A bootleg hair dye business would in all likelihood develop promptly with resultant danger to users as a result of inferior products. This would be virtually impossible for the Government to control.

AS REGARDS OUR OWN COMPANY

1. Our major product is TIZ— creme and color rinse (approximately 85 percent of our business). TIZ— is a temporary hair dye which does not change the basic color of the hair but gives the hair color casts. TIZ— has never been made from certified colors. (Exhaustive tests have proved we cannot give results satisfactory to the consumer when certified colors are used.) We will, therefore, be out of business if the hair dyes exemptions are repealed.

2. In the interests of public safety and for our own reputation we have made it a practice to have Dermatitis and allergenicity tests performed on our products by a highly reputable laboratory—the Laboratory of Vitamin Technology in

Chicago. Our products passed these tests or we would not have sold them. We are confident all other reputable companies in our industry run similar tests.

3. Since 1951 we estimate that over 250 million applications of our hair dye have been given in beauty salons or at home. The attached letter from our insurance carrier will testify to the safety of our products, the premium rate reductions our products have earned, and the minute number of complaints we have received compared with the number of applications given.

4. Our company has outgrown three plants. At present, over 200 people are directly dependent on the prosperity of our company for their support. As stated previously, repeal of the hair dyes exemptions will result in their immediate unemployment.

In conclusion, we started as the very smallest of small businesses. We are still small business, but small business or large, we can't believe it is the intention of the Government to penalize a company, its employees or in a larger sense, a major industry and 15 million satisfied users of today's hair dyes. This would certainly be the case if the hair dyes exemptions are repealed.

CHICAGO, ILL., *June 11, 1962.*

Mr. C. P. PROSSER,
M. Pier Co., Inc.,
Pompano Beach, Fla.

DEAR MR. PROSSER: In accordance with your request we wish to give you the following information.

The Continental Casualty Co. has handled the insurance of M. Pier Inc. and its subsidiaries since 1951. We do not have audit figures of sales dating back that far, but we do have a list of the total premiums that you have paid to date which aggregate $30,890.96. Therefore, if your sales since 1956 aggregate $6,837,957 all you need to do is to take from your own records your sales down to 1951 and add it to this figure. I imagine that they would be well in excess of $9 million.

Since 1951 you have reported a total of 39 complaints or claims. Thirty-four of these cases have been settled for total payments of $2,947.95. The majority of the complaints were without foundation, they aggregate, if anything, only nominal injuries and most of the payments made were in an effort to preserve the business relationship between you, our assured, and your customer. None of these claims, in our opinion, could have been substantiated and certainly they would not have occurred had your products been used in accordance with your printed directions.

Since 1951 your premium rate has been reduced periodically to the point that the present rate is $2.25 per $1,000 of your sales. In addition, we have greatly increased the limits of liability under your policy. Under your current policy which expires July 26, 1962, there have been a total of five claims presented. Two cases have been settled for a total payment of $550 and there are three pending of doubtful value. We would classify practically all of those paid as of the nuisance variety.

I have no way of knowing how many millions of applications of your products have been made, but perhaps you can determine this from your own sales records. However, from the information given above we can state that as far as we are concerned, you have an excellent record and this has been reflected in the steady lowering of your rates.

If there is any additional information that I can give you, please advise.

Sincerely,

W. H. ALGER.

NATIONAL AMERICAN COSMETOLOGY SCHOOLS, INC.,
Newark, N. J., July 5, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CHAIRMAN: This statement of protest against H.R. 11582—and particularly section 103 thereof—is filed on behalf of the membership of this national association, embracing more than 750 private beauty culture schools located throughout the United States.

Individually owned, these private training schools represent an overall investment of many millions of dollars. They employ thousands of instructors,

plus general office help and maintenance workers. They teach upward of 125,000 students annually.

All of these schools and their owners, every instructor, every clerical worker, every maintenance employee, and every student can be adversely affected by passage of this unnecessary and unwarranted measure.

This association stands solidly in favor of legislation that benefits the entire beauty culture industry and is in the interest of the countless millions of women who patronize the Nation's estimated 150,000 beauty salons.

But this legislation is neither in the interest of this industry nor in the interest of women generally.

Instead, its immediate effect would be economic disaster for the entire beauty profession, since it would immediately deprive every salon of a service that now constitutes a major portion of its billion-dollar income.

Likewise manufacturers would be adversely affected, and their employees discharged.

Approximately 500,000 beauty salon operators would suffer loss of income with loss of employment by many. Owners of these salons would be faced with the loss of millions of dollars of life's savings now tied up in beauty shop investments.

Aside from the indicated effect upon school owners and instructors, the 125,000 students now in training in beauty schools would suddenly find that their future in the beauty industry is in jeopardy and the huge sums invested in tuition would have greatly lessened value.

The ostensible purpose of this staunchly opposed measure supposedly is protection of the public. With due respect, we ask: "Protection against what?"

The Government already provides protection against possibly ensuing allergies in its present requirements for patch tests, and the record of haircoloring to date show that such unfavorable reactions as may occur are infinitesimal against the total services rendered and are due to occasional allergies.

Surely, the great efforts and the millions and millions of dollars spent in research by the laboratories of our hair-coloring manufacturers have not been devoted to building products whose qualities are inherently toxic. They have been—and are—devoted to creating beauty with safety.

Removal of the special exemptions now accorded hair dyes not only can create economic chaos in this billion-dollar industry, but unemployment figures and relief roles will be swelled to record highs—all without need.

We respectfully urge your committee to reject this measure, particularly section 103.

Very truly yours,

BENEDICT V. GRIPALDI, *President.*

GODEFROY MANUFACTURING CO.,
St. Louis, Mo., June 18, 1962.

Re. H.R. 11582.

Hon. OREN S. HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR SIR: We respectfully submit our objection to H.R. 11582, which is now before you and your committee. We address ourselves particularly to section 103, which removes the exemption for coal tar hair dyes.

This company has been manufacturing cosmetics since 1882, and coal tar derivative hair dyes since 1894. Over this span of years many millions of applications of our hair dyes have been made, and only an infinitesimally small number of persons have experienced allergic reactions, the result of the failure of the user to follow the directions for patch testing. Hair dyes have a favorable ratio with thousands of other products consumed by the American public.

Constant research is being made by this firm, and many others, but to date only the coal tar derivatives produce a satisfactory hair coloring which meets the needs of the consuming public. These products have become an economic necessity for hundreds of thousands, as it is estimated that 15 to 30 million men and women regularly color their hair.

Banning hair dyes from the legitimate market would have far-reaching dire effect. The consuming public would be deprived of a satisfactory product; thousands of beauty salons whose revenue from these services are vital to their existence would suffer; and likewise, many thousands of persons engaged in the manufacture and sale of these products would be without employment. Elimi-

nating business amounting to $600 million or more can only further help to damage our already jittery economy.

This firm, which has been established since 1882, would be forced to close its doors as over 95 percent of our business is, and has been the manufacture of coal tar derivative hair dyes. Surely, this is not the time to enact extreme hardship measures which experience proves are not warranted. We urge your favorable consideration of continuing to protect the consumer by the retention of the present hair dye exemption, and thereby retaining the buying power of hundreds of thousands now employed in the manufacture, sale and distribution of these products.

Respectfully submitted.

E. L. EMME, *General Manager.*

D. E. WINEBRENNER CO., INC.,
Hanover, Pa., May 31, 1962.

HON. GEORGE A. GOODLING,
House Office Building,
Washington, D.C.

DEAR MR. GOODLING: It has come to our attention that public hearings will begin June 19, 1962, on H.R. 11581 (drug and factory inspection amendments) and on H.R. 11582 (pretesting of cosmetics).

We as food manufacturers are definitely opposed to these two amendments because such unlimited power is not only unnecessary but subject to possible misuse by inexperienced Food and Drug Administration field inspectors. Mandatory inspection should not extend to the food field, to a manufacturer's processes and formulas, to his complaint and personnel files, or to his private consulting laboratory. Exercise of such broad power endangers property rights and valuable formulas and trade secrets, and may well operate to discourage industry from keeping important research and quality control records. Therefore the enactment of H.R. 11581 should be opposed by food manufacturers unless the bill is amended by striking all of "Title II—Clarification and Strengthening of Factory Inspection Authority."

H.R. 11581 proposes new factory inspection power which goes beyond anything reasonably required for enforcement of the Federal Food, Drug and Cosmetic Act. Section 704 of the act is first amended to cover a manufacturer's consulting laboratory as well as his own establishments. Next, the bill amends section 704(a)(2) of the act to bring under factory inspection "all things therein * * * bearing on violations or potential violations of this Act." Finally, section 302(a) is amended to strike (f) thus enabling the FDA to force an entry by court order if a factory manager refuses to permit inspection.

Considering the new language proposed for section 704(a)(2) there would appear to be no limits that a food manufacturer can place upon the demands of an inspector, even where the records and things called for seem irrelevant to the statutory objective of preventing adulteration or misbranding. Apparently an inspector could cite this broad authority to require a manufacturer's disclosure of consumer complaints, secret formulas and patents, personnel qualifications, quality control and laboratory records, and office documents dealing with production, packaging, labeling, advertising, marketing, pricing and financing. Any doubt that the FDA would have an interest in financial and economic records tends to disappear in the light of recent enforcement actions dealing with such matters as "cents off" promotional labeling and "economy size" package designations.

Less than 10 years ago the food industry cooperated with the FDA in enacting the compulsory factory inspection amendment of 1953. At that time Congress was quite firm about limiting inspection powers to matters reasonably related to the prevention of violations. It specifically declared against "fishing expeditions" designed to obtain evidence for legal prosecution and it confined inspections to matters of sanitation.

The food manufacturer must oppose excessive factory inspection, not because he has something to hide, but because he has a right and duty to protect his private property in valuable formulas, trade secrets, etc., and also because consequences detrimental to consumers may result from a policy of unrestricted inspection. As regards secret formulas, etc., a manufacturer observes that inspections may be made not only by Federal agents but by commissioned State

and municipal agents as well. He notes that these inspectors may leave government service to become employees of a competitor, and that it would be difficult in any case to prove an unlawful breach of confidence, whether deliberate or inadvertent, with respect to trade secrets. As regards consumers, the manufacturer sees a prospect of harm in the fact that unrestricted inspection discourages the keeping of many records important for quality control and research. Above all, the food manufacturer sees in this amendment a shift from traditional FDA inspection practices to a system of search and seizure. And he remembers that violation of the Federal Food, Drug and Cosmetc Act can mean a personal criminal conviction even in the absence of guilty knowledge or intent.

H.R. 11581 was drafted by the FDA as a result of the drug industry investigation conducted by Senator Kefauver's antitrust subcommittee. The bill principally affects drug products, and it probably would never have involved food at all had there been separate food and drug provisions for inspection as in the case of the adulteration and misbranding sections. Drug manufacture differs from food manufacture in many respects, and what is necessary for one may be unwarranted in the case of the other. The desirable solution of this problem is to revise H.R. 11581 so as to eliminate drug references from existing section 704(a) of the Federal Food, Drug and Cosmetic Act, and to enact a new section 704(b) which will specifically govern drug factory inspection. The food industry would have no reason to oppose enactment of a separate drug inspection provision, especially if its form were sound and it invited the support of that industry.

Please excuse the length of this letter; however, we are very seriously concerned about the outcome of this proposed amendment, and we ask that you oppose it in behalf of all food manufacturers in your district as well as ourselves.

With kindest regards, we are,

Most sincerely,

WIRT S. WINEBRENNER,
Vice President.

STATEMENT OF NATIONAL COUNCIL OF FARMER COOPERATIVES ON H.R. 11581 AND H.R. 11582

The National Council of Farmer Cooperatives is a national federation of 127 farmer-owned and farmer-controlled cooperative marketing and purchasing associations, which are local, State, regional, and national in scope. Our affiliates include 5,700 farmer cooperatives throughout the Nation serving 3 million farmer memberships.

We wish to express our views on three particular subject areas contained in H.R. 11581 and H.R. 11582. They are:

(1) Permitting an exemption for feed and color additives causing no harm to animals and leaving no residue in food produced for human consumption as provided for in H.R. 1582, title III, sections 302 and 303.

(2) Broadening the Secretary's powers of factory inspection as provided for in H.R. 11581, title II, section 201.

(3) Using H.R. 11581 and H.R. 11582 for the establishment of uniform standards of quality and sanitation applicable to domestic and imported products.

FEED ADDITIVES LEAVING NO RESIDUE IN FOOD FOR HUMANS

Approximately one-fourth of the national council members own and operate feed manufacturing facilities producing animal feeds for the livestock, dairy, and poultry industries. According to the USDA Farmer Cooperative Service, farmer cooperatives produce 24 percent of the total animal feed manufactured in the United States.

With this broad membership interest in mind, the national council wishes to express its views on the use of feed and color additives in animal feed as stated in H.R. 11582, title III, sections 302 and 303. Section 302, as it is written, will give authority to the Food and Drug Administration to grant an exemption for the inclusion of food and color additives in animal feed which are harmless to the animals and leave no residue in the product processed or prepared for human use. New permits for the inclusion of diethylstilbesterol in animal feeds have not been granted since the passage of the Delaney amendment in 1958, nor have intracompany transfer of permits from an outmoded plant to a new

facility been granted. Enactment of this section will establish a sound procedure whereby the FDA will permit animal feed manufacturers again to use additives which have been helpful in improving growth, lowering feed conversion rates, and enriching the appearance and value of their products produced for the livestock, dairy, and poultry industries. Improvements in feed efficiency and growth with the corresponding decreases in costs of production have been mostly passed on to the American consumer in the form of lower costs of animal products.

We are opposed, however, to the unlimited discretionary power given to the Secretary in determining the "zero residue" requirement. We urge that section 302 be further improved by amendment to take into account the best scientific judgment available.

At the 1960 annual meeting of the National Council of Farmer Cooperatives, the delegates approved the following:

"* * * The council proposes that there be established an impartial commission to review applicable legislation now in effect with a report of its findings to the President or the Congress. Such commission should also report and recommend such administrative procedures as will give adequate protection to consumers, but at the same time protect producers from intemperate, unreasonable, and precipitate action by Government agencies which would result in serious loss to them * * *."

In 1960, the President's Science Advisory Committee made several significant recommendations, the standards and operating procedures of which, in our judgment, should be incorporated in section 302 and 303. The Science Advisory Committee, in 1960, stated:

"1. That the Secretary of Health, Education, and Welfare appoint a board advisory to him to assist in the evaluation of scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds.

"The advisory board should be composed of scientists from the National Cancer Institute, the Food and Drug Administration, the U.S. Department of Agriculture, and the scientists outside of Government from a panel nominated by the National Academy of Sciences.

"It would be the function of the board to weigh evidence and to make recommendations to the Secretary of the Department of Health, Education, and Welfare on the basis of available scientific data, both on applications for approval of new food additives and in all cases where the withdrawal of a prior approval or sanction is under consideration. The board would consider among other matters:

"(*a*) Whether or not the tests for carcinogenicity are appropriate and reasonable,

"(*b*) Whether the substance is or is not in reality carcinogenic as determined histopathologically or by other criteria,

"(*c*) Whether addition of the substance to agricultural products would result in a concentration of the substance above the natural background level of such substance.

"(*d*) What assay techniques are appropriate to determine whether a specific carcinogen is present in food.

"It would also be the function of this board to review from time to time its recommendations and to modify them in the light of new scientific knowledge. Further, the board would assume the responsibility of recommending to the Secretary of Health, Education, and Welfare specific research problems to be undertaken to provide necessary scientific data.

The national council supports the statement of the President's Science Advisory Committee and recommends that appropriate language be incorporated in sections 302 and 303 to take advantage of the competent efforts of the advisory committee to establish sound procedures and safeguards for the protection of consumers and manufacturers using feed and color additives.

Incorporating the recommendations of the Science Advisory Committee into sections 302 and 303 will broaden the scientific data available to the Secretary, while at the same time, assure the user of the feed and color additives fair and impartially imparted information for men and women of competent scientific achievement.

It is scientifically and politically unwise to seek tolerances for additives known to induce cancer, nor do we make such a request. However, it must be recognized that there is serious controversy among scientists on the methods and

techniques employed in determining residues in various products. It is from these methods and techniques that many of the past decisions of the Food and Drug Administration have been rendered, many of which, in our judgment, are based on inconclusive or disputed scientific evidence. The President's Science Advisory Committee in 1960 commented on this subject:

DEFINITION OF INDUCED CANCER IN ANIMALS

"The recommendation procedure for testing the possible carcinogenicity of a chemical additive calls for its incorporation into the diet of several animal species, at several dosage levels, and for the duration of the animal's life span where feasible. Like all biological assay methods, this procedure has more inherent variables than do procedures involving physical and chemical methods. Further, recognition of a carcinogen by the bioassay technique presents greater difficulties of interpretation than are usually encountered in assaying the effects of other pharmacologically active substances. These difficulties of interpretation are related to the identification of the tumor as a cancer, and to the way in which the experiment is designed.

"The criteria for defining whether or not a 'cancer' has been induced in the experimental animal are varied. They include the microscopic appearance of the tumor (histopathology), its ability to metastasize, its transplantability to other animals of the same species or inbred strain and its local invasiveness. The most commonly employed criterion is the histopathological diagnosis. However, this depends on the judgment of pathologists and diversity of opinion among them is not uncommon. A further difficulty emerges from the fact that not all tumors are cancers and that there is a difference of opinion regarding the possible, subsequent malignancy of at least certain benign tumors."

Further, techniques that are currently available and in use may not be able to find residues in food prepared for human use. Yet, in a short time, improvement of current techniques may enable scientists to find traces of residue. With the constant advancement in scientific techniques, this is far more than a remote possibility. If this occurs, the law would require the immediate cancellation of all permits even though no change occurred in the product. The helpful aspects of sections 302 and 303 to the animal feed manufacturing industry would then be negated.

AUTHORITY TO BROADEN HEALTH, EDUCATION AND WELFARE'S POWERS OF FACTORY INSPECTION

The national council believes H.R. 11581, title II, section 201 will give the Secretary of Health, Education, and Welfare unnecessary and undesirable powers to search the premises and records of the manufacturers, processors and packers of food products for human use. The broad and sweeping language in section 201 would grant inquisitorial powers since no need for the search and inspection action has to be shown. It would authorize "fishing expeditions" for violations.

The Secretary currently has the right to inspect premises to determine sanitation practices and the adequacy of processing equipment, when it is known that a manufacturer or processor has placed an adulterated food product in the marketing channels. However, the amendments offered in section 201 will permit a "search" of records, including formulation procedures and data, personnel files, processing procedures and other private papers. Such "searches" create grave danger of a "leak" of confidential information if employees of FDA leave for private industry assignments. The passing on of vital information to competitors might well cause irreparable harm to the business income of the manufacturer or processor of food products involved in such inspections.

We can readily understand, for the protection of the public, that when adulterated food products are found in the channels of distribution, the FDA should have the authority to investigate sanitation practices, raw materials and the adequacy of processing equipment of the suspected offenders. FDA has much authority in this field now. Modest expansion of this authority to remove adulterated food from marketing channels may be desirable to protect public health.

However, section 201, in our judgment, would grant authority far in excess of that necessary to protect the consuming public. We are strongly opposed to this section and recommend it be deleted from H.R. 11581 or FDA be re-

quired to show good and sufficient cause before search warrants for specific items relevant to protection of public health would be granted.

USE OF H.R. 11581 AND H.R. 11582 FOR ESTABLISHING UNIFORM STANDARDS OF QUALITY AND SANITATION APPLICABLE TO DOMESTIC AND IMPORTED PRODUCTS

These bills and the authority they would grant the Department of Health, Education, and Welfare should be directed toward the maintenance of comparable standards of quality and purity for imported as well as for domestic food products. At the 1959 annual meeting of this organization delegates approved the following policy statement:

"*Inspection of food imports.*—Food coming into the United States is not subject to a Federal Food and Drug Administration inspection of their producing premises and is subject only to inspection of the finished product itself. * * *

"We urge that Congress take action to require the Food and Drug Administration to apply comparable sanitary standards to all food products whether produced in the United States or in a foreign land."

These bills strengthen the inspection authority of the FDA regulations for domestic production of foods, drugs, and cosmetics. This organization has many members in the field of processing and marketing of food and fiber products. They and other food manufacturers have voluntarily established high standards of quality and sanitation—at increased cost—to protect consumers and to raise demand for their products. This action might incidentally place our manufacturers at a competitive disadvantage if foreign plants should resort to the shipment of substandard products, and inspection in consumer channels does not disclose the use of comparable plant standards and raw material standards. We recognize that the canning and processing facilities and premises of foreign food manufacturers are not available for inspection on the same basis as are U.S. food processing plants. Even though comparable U.S. inspection is not available, uniform standards applicable to the final product may encourage the governments of foreign countries to establish high sanitary standards for raw materials and plant facilities in order to protect consumers as well as to develop more equitable competitive standards in foreign and domestic commerce.

We believe the establishment of uniform sanitary standards is desirable, not only from the standpoint of establishing a fair and equitable competitive climate in the retail markets for food and fiber products, but to protect the consumer against wide variations in quality and value of the products they purchase from whatever source.

SUMMARY

We recommend the passage of sections 302 and 303 of title III of H.R. 11582 provided the Secretary of Health, Education, and Welfare be required to have available and to take into account broad, scientific information and procedures as recommended in the report of the President's Science Advisory Committee. Action taken contrary to the recommendation of such an advisory committee should be reported to Congress with justification therefor.

Further, H.R. 11581 and H.R. 11582 will strengthen the inspection authority of the FDA regulations for domestic production of foods, drugs and cosmetics. This organization has many members in the field of processing and marketing of food and fiber products. They and other manufacturers have voluntarily established high standards of quality and sanitation—at increased cost—to protect consumers and to raise demand for their products. We believe the establishment of uniform sanitary standards desirable not only from the standpoint of establishing a fair and equitable climate in the retail markets for food and fiber products, but to protect the consumer against wide variations in quality and value of the products they purchase from whatever source.

Section 201, title II, H.R. 11581 will give the Secretary of Health, Education, and Welfare unnecessary and undesirable powers to search the premises and records of the manufacturers, processors and packers of food products for human use. The Secretary currently has the right to inspect the premises to determine sanitation practices and the adequacy of processing equipment, when it is known that a manufacturer or processor has placed an adulterated food product in the marketing channels. We believe this is ample authority. Section 201, in our judgment, would grant authority far in excess of the necessary to protect the consuming public. We are strongly opposed to this section and recommend that it be deleted from H.R. 11581 or the FDA be required to show good and

sufficient cause before search warrants for specific items relevant to protection of public health would be granted.

NATIONAL COUNCIL OF FARMER COOPERATIVE POLICIES

Opportunity for trade.—Various devices, such as quotas, licenses, seasonal embargoes, bonus dollars, and many other restrictions, have become of even greater significance in regulating and restricting international trade than tariffs. As a consequence, in the presence of such highly restrictive measures, tariffs assume subordinate importance as a bargaining instrument.

The expansion of exports and international trade will come from increased economic strength in foreign countries, currency convertibility, the development of the proper climate for capital investments, particularly in the newly developing areas, and the elimination of the many practices which hamper rather than encourage the exchange of commodities. We recommend these principles.

Inspection of food imports.—Food coming into the United States are not subject to a Federal Food and Drug Administration inspection of their producing premises and are subject only to inspection of the finished product itself.

American-produced food products are subject to an inspection of producing premises and foods emanating from such premises can be seized if they are produced "* * * under insanitary conditions where it may have become contaminated * * *."

We urge that Congress take action to require the Food and Drug Administration to apply comparable sanitary standards to all food products whether produced in the United States or in a foreign land.

In addition, the National Council of Farmer Cooperatives seeks specific congressional action, during the 1959 session of Congress to require the Food and Drug Administration to apply comparable sanitary standards to all food products whether produced in the United States or in a foreign land.

Food and Drug Act administration of agricultural chemical regulation.—The administrative procedures followed by the Department of Health, Education, and Welfare with respect to laws governing the use of certain agricultural chemicals used in the production or preservation of foods or feedstuffs said to be harmful to consumers, have created deep concern among farmers of the Nation.

The health and well-being of consumers of farm products is of paramount interest and concern to producers of those products. Yet conflicts in findings of two Government agencies with responsibilities in this field give rise to serious question as to the value of legislative requirements of such rigid nature. Such requirements are held by distinguished scientists to be unreasonable.

The council proposes that there be established an impartial commission to review applicable legislation now in effect with a report of its findings to the President or the Congress. Such commission should also report and recommend such administrative procedures as will give adequate protection to consumers, but at the same time protect producers from intemperate, unreasonable, and precipitant action by Government agencies which would result in serious loss to them.

Such commission should also make recommendations with respect to adequate research on improved agricultural chemicals and methods of application and use which will safeguard consumers.

In the interim we insist that the administration of the pure food and drug laws governing use of agricultural chemicals used in the production or preservation of foods and feedstuffs be tempered with as much reason and concern for farmers as for consumers. This would entail proper information to farmers as to proper methods of application, prior warning before commodities are condemned with ample time and opportunity to be heard and to take corrective action before condemnation.

EVANS RESEARCH & DEVELOPMENT CORP.,
New York, N.Y., July 5, 1962.

Re H.R. 11581 and H.R. 11582.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: In accordance with your permission dated June 15, 1962, we would like to make the following statement for the record.

The proposals contained in the H.R. 11581 and H.R. 11582 which would allow unlimited inspection of consulting laboratories seems to us entirely unnecessary and constitutes a definite hazard to the rights of consulting laboratories, their clients, and the Federal Government.

There are several different types of laboratories called consulting laboratories; many of them do basic research for industrial clients and often Government agencies as well. They also do product development in many different areas for both industrial clients and the Government. In many cases the Government contracts involve confidential and secret research. Only qualified and U.S.-cleared personnel are allowed access to these records. It is obvious that such agreements with the Government to maintain proper safeguards against the disclosure of records involved in such work would have to be maintained and would be in direct conflict with the proposed legislation.

The very lifeblood of our American economy has been the development of new products and the patent system which offers them protection. In many cases a small variation in formulation or process is the difference between a superior product, from a customer's standpoint, and a less desirable one, even though both would pass any inspection of raw materials, processing, etc.

In our opinion it would also be an unnecessary burden of expense to the laboratories being inspected to have to furnish the personnel to observe and explain activities and furnish the necessary cooperation to make the information required available.

If any inspection of consulting laboratories is granted to the Food and Drug Administration, it should be strictly limited to such control work as may be carried on by the laboratory directly in connection with the actual manufacturing process of products to be used by the public and should not relate in any way to research and development of new and different products and methods.

We respectfully submit that the destruction of private rights, which would be occasioned by this legislation, plus the burden of carrying out the activities, far outweigh any possible minor value to the common good which might be derived.

Respectfully,

WILLIAM E. HOLLAND, Ph. D.,
Vice President.

SALES AFFILIATES, INC.,
New York, N.Y., July 11, 1962.

Re H.R. 11581 and H.R. 11582.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR SIR: This organization is a New York corporation with its principal office located at 801 Second Avenue, New York, N.Y. We distribute our own brands of professional permanent waves, hair colorings, cosmetics, and similar items through wholesalers to the beauty trade for use by licensed operators in beauty salons. The factory is located in Waterloo, Seneca County, N.Y., and has been for 20 years the principal business in that community. While we are far from the largest organization in our industry, we are also not the smallest.

In accordance with permission granted on June 13, 1962, we hereby file the following statement of our views of the above bills pending before the Committee on Interstate and Foreign Commerce.

H.R. 11581, TITLE II

We object to sections 201, 202, and 203 of title II of this proposed bill, which sections relate to the inspection of factories and consulting laboratories.

We believe that the authority for factory inspection granted by section 201 is so far reaching as to be plainly violative of the fourth amendment of the Constitution of the United States. Authority is here sought to be given to Government agents to enter any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction, and to inspect such factory, warehouse, establishment, consulting laboratory, and all pertinent equipment, finished and unfinished materials, containers, and all records, files, papers, processes, controls and facilities therein.

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All of this search and inspection may be done without the prior showing of any necessity whatsoever for doing them. Correlative with these acts will be the disclosure of secret formulas, processes of manufacture, and other valuable trade secrets which are the very lifeblood of the business of the person whose business premises (or home) are the subject of the search. It is well within the realm of possibility that these secrets may soon find themselves in the possession of a competitor after their disclosure.

Consulting laboratories are universally researching and developing new ideas, many of which have no present commercial application. As proposed, this bill would require flagrant violations of trust and lay bare to the inspecting Government agents all of the most secret records, files, papers, processes, controls and facilities which show the results, as well as the work in progress, of such a laboratory, causing irreparable and unnecessary damage to the laboratory and its clients, without one iota of benefit inuring to the public interest. Should such a right exist in the Government, it is easy to visualize a great curtailment in research, with the inevitable result that private consulting laboratories would soon find themselves without clients and in the process of liquidation, thus completely depriving the public of the great benefits which accrue from such research.

Furthermore, research in the field of cosmetics is generally a small part of such laboratories' work. Most of these laboratories are engaged in a multitude of research problems, many of which have nothing or little to do with foods, drugs, or cosmetics. To compel disclosure of the innermost secrets of such work would be absolutely irrelevant to the protection of the public from harmful foods, drugs and cosmetics, grossly unfair to the laboratory and its clients, and cause untold harm to the public interest.

Should the Government be granted any right of inspection of consulting laboratories that right should be limited strictly to the inspection of control tests conducted in connection with the actual manufacture of products for sale to the public and should specifically be denied as to research and development activities.

H.R. 11582, TITLE I, SECTION 101

Section 101 provides for the approval prior to marketing of all new cosmetics.

While we cannot fault the purpose of this section, we most respectfully direct your attention to the fact that under the provisions of the present food, drug, and cosmetic law the Food and Drug Administration is fully armed with authority to seize and prosecute speedily any harmful cosmetic which may find its way to the marketplace. Since the enactment of the present law, there have been very few dangerous cosmetics marketed. The proof of this statement is evidenced by the very small number of seizures of cosmetics made by the Food and Drug Administration during the past several years; and the fact that so few seizures have been necessary is also proof the manufacturers of cosmetics do make sure their products are safe before the products are marketed. In some instances, such as those of a fingernail adhesive and a home hair waving solution, the harmful propensities of the products were not discovered (and probably could not have been discovered) during premarket testing but were found only after millions of applications of each product had been used. In all likelihood the proposed law would not have uncovered the harmful propensities of these products; for like so many of the new miracle drugs which have been granted Food and Drug approval the full nature of all possible side reactions to such cosmetics could only be determined finally by their actual universal distribution and mass usage. When the harmful possibilities of these products were discovered they were promptly removed from the market.

This proposed legislation is plainly discriminatory against the small- and medium-sized business and in favor of the giant cosmetic manufacturer. Without question, and of necessity, the general test procedures which would be established under this law to cover a wide variety of products for many different uses, would go far beyond the test procedures now needed to determine the safety of any particular product and the dangers to be anticipated from its sale and use. Because of his size and wealth, the large manufacturer will be able to afford to spend the huge sums of money the required generalized testing will entail. The small firm, and even the fairly large firms, will not be able to afford to expend the large sums of money unnecessarily required for this generalized testing, and they will be forced out of business. Their business will be gobbled up by the big firms, and a few giants will then control the entire cosmetic industry.

H.R. 11582, TITLE I, SECTION 103

Section 103 seeks the repeal of special exemptions for hair dyes.

We have sold and distributed the permanent type of coal-tar hair dyes to the beauty trade for more than 30 years. Our records since January 1, 1959, show that we have sold many millions of applications of the permanent and temporary types of these products and that we have had few reports of alleged injuries resulting from their application during that time. These reports have been received at the phenomenal ratio of about 1 alleged injury per 2,800,000 applications sold. Furthermore, none of these alleged injuries was of a serious nature nor has any lawsuit been commenced by anyone of those reporting alleged injuries.

And not a single report of alleged injury was received during that period resulting from the application of the permanent type of coal-tar hair dye which we market.

Insurance companies issue product-liability insurance on an extremely realistic basis. The rates are based on actual experience. Our company carries a liability policy on all of its products with high limits of liability. The primary rate charged for our hair colorings is less than the rate which is charged for our face and hand creams and lotions, shampoos, etc., and only one-half the rate charged for permanent waving solutions.

All of the said reports of alleged injuries which we have received on hair colorings were based on claims of allergic reactions to some product contacted by the user. In several of the alleged instances, the offending allergen may well have been the shampoo, the wave set, or some other product contacted at or about the time of the application of the hair dye and not the hair dye itself. So far as allergy is concerned, there are hundreds of common foods and drugs in universal use which have a much higher incidence of allergic reactions to them by susceptible persons than do the coal-tar hair dyes. Shellfish, strawberries, milk, eggs, etc., are all offenders. Aspirin, iodine, adhesive tape, ad infinitum are all allergens to large groups of susceptible individuals.

At a hearing before the Food and Drug Administration held in Washington on January 6, 1956, Dr. Adolph Rostenberg, a consultant for the Food and Drug Administration, testified to the effect that the patch test was prescribed by the present Food, Drug and Cosmetic law was a highly accurate means of discovering whether or not a prospective user of coal-tar hair dyes was allergic to the product.

Dr. Louis Schwartz, former medical director of the U.S. Public Health Service, testified at the same hearing to the effect that the incidence of allergy to paraphenylenediamine hair colorings (paraphenylenediamine is a chemical commonly used in the permanent type of hair dyes) was low; that he had examined thousands for incidence of allergy to such dyes and it was nil. His testimony further showed that of millions of bottles of a well known permanent type of coal-tar hair dye sold, a ratio of less than 0.00001 percent complained of alleged allergic reactions.

No one has ever claimed that hair dyes were toxic or poisonous. The incidence of injury due to allergic reaction is much too small to justify the proscription of these widely used products.

There are over 150,000 beauty shops in the United States. Over 800,000 persons are employed in the beauty shop industry. Gross income received by beauty shops tota's over $2,500 million a year. Hair coloring is estimated to constitute over 40 percent of the business of these beauty shops. Without hair-coloring business, few of the 150,000 beauty shops could survive, and hundreds of thousands of idled hairdressers and other employees would greatly expand the already large body of unemployed.

Drug and department stores sell millions of dollars worth of hair dyes yearly. Should section 103 be adopted, these stores would lose an important segment of their business.

Despite the economic disaster which would follow the outlawing of hair colorings, we would not urge it as an excuse for permitting the sale of coal-tar hair dyes if such sale were not amply justified. However, from all of the facts available it must be clear to any impartial observer that there is no justification whatsoever for prohibiting the sale and use of these materials.

Millions of women today color their own hair or have it colored in beauty shops. They will not willingly abandon the use of hair colorings for the enhancement of their personal appearance. Should legitimate hair colorings be removed

from the market by the passage of section 103, these women will surely resort to the use of the bootleg hair colorings which will most certainly flood the market. The positive harm to these women in such an event is incalculable. They will demand hair colorings. Their demand will be met by fly-by-night peddlers. A multitude of impure and potentially dangerous concoctions, produced under most unsanitary conditions, will fill the vacuum created by the forced withdrawal from the market by legitimate manufacturers of the present eminently safe and pure hair colorings with which the unscrupulous cannot now compete.

CONCLUSION

For all of the above reasons, we most urgently request that approval of tile II—Clarification and Strengthening of Factory Inspection Authority, of H.R. 11581, and title I—Premarketing Clearance of Cosmetics for Safety, of H.R. 11582, be withheld by your committee.

Respectfully submitted.

RALPH L. EVANS, Ph. D.
President.

NATIONAL COTTON COUNCIL OF AMERICA,
Washington, D.C., July 17, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Washington, D.C.

DEAR MR. HARRIS: The purpose of this letter is to advise you of the views of the National Cotton Council on H.R. 11581 and H.R. 11582. The National Cotton Council is the overall organization of the raw cotton industry, representing cotton farmers, cotton ginners, cotton merchants, cotton warehousemen, cotton spinners, and cottonseed crushers.

Since cottonseed oil is a food product and cottonseed meal is used as an animal feed, we are interested in these bills and their possible effects on the consumption and use of these products.

Our concern about H.R. 11581 is with title II, section 201. This section confers upon the Secretary of Health, Education, and Welfare broad authority to enter the premises of manufacturers or processors of food products for the purpose of inspecting their production facilities and procedures. It further authorizes the examination of records maintained by such establishment.

We oppose this section as an unwarranted grant of power. While some type of inspection may be necessary to meet the requirements of the Federal Food, Drug and Cosmetic Act, it should at least be based upon good and probable cause as determined by a responsible officer of the Government and not upon the discretion of a Federal employee designated to perform such inspection.

With respect to H.R. 11582, we support section 302. This section would permit an exemption from the so-called Delaney cancer clause for feed and color additives in animal feed upon a finding by the Secretary that such additive will not adversely affect the animal and that it will leave no residue in any part of the animal prepared for human use.

This is desirable for several reasons. It can help to avoid some of the serious consequences of previous applications of the Delaney clause. It would also relieve the inflexibility of existing law and introduce reasonableness into its administration. The highly restrictive nature of present law could hamper the development of agricultural chemicals which are vital to maintaining efficiency in U.S. agricultural production. The narrow application of existing law has and can result in severe financial losses to farmers and others dealing with agricultural commodities without necessarily reducing the incidence of cancer in human beings.

We believe that section 302 is a desirable addition to existing law and urge its enactment.

We would appreciate having this letter included in the record of hearings on this legislation.

Sincerely,

J. BANKS YOUNG.

VERSIS FOODS, INC.,
Washington, D.C., June 21, 1962.

Hon. OREN HARRIS,
House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The Constitution of the United States of America guarantees every citizen of this country of ours the right of "due process of law." This is the right (not the privilege) which lies at the heart of our respect for the individual and his privacy. This right protects every individual from the abuses which can occur when individual persons are given lead to use their prerogative.

Presently, I believe that any court of this land may subpena any record it wishes to look through. The process of subpena is involved and time-consuming especially when other legal processes are employed to slow it down. We realize this and we realize that these procedures make it possible for some persons to evade the law. Now the basic question you are challenging is whether it is better to let some extra legal operators escape while we give all men every opportunity to protect their privacy or whether we choose to leave no individual privacy in the hopes of catching a few dumb crooks.

To me the preferable choice is obvious, especially considering the logical fact that a smart crook won't put anything on paper. My individual rights and privacy and yours, and the privacy of all Americans is worth more than the opportunity to clamp now on a few operators who can be caught in other ways, although not as easily.

Operators who are found to be violating the law, whether through carelessness or intent, could be given probationary periods to prove their good faith. During these periods, these violators could be prohibited from any Federal, State, or other bid. This would be a definitely positive force in correcting any deviations from the law and feel that this system would honor the individual who obeys the law as it punishes the lawbreaker. The present system you propose would at least be troublesome, annoying, and even economically harmful to the law-abiding citizen as well as the violators whom it only might bring to light.

America, as the land of freedom, has grown more rapidly than any other country before or since. In order to remain the land of freedom, and to continue to grow, we must protect the individual and his rights as diligently as if our existence depends on it for in truth it does.

Sincerely,

A. S. VERSIS.

AMERICAN CONGRESS OF PHYSICAL MEDICINE AND REHABILITATION,
Chicago, Ill., May 31, 1962.

HON. OREN HARRIS,
Chairman, Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: Enclosed is a copy of a resolution which was unanimously supported by our organization of more than 600 physicians at our last annual session, August 1961.

Our organization is composed of physicians who have a major interest in the field of physical medicine and rehabilitation. In our practice we use many of the devices which come under the purview of the Food and Drug Administration. Therefore, we are most anxious to support legislation which will provide better protection for our patients as well as the public at large.

Yours very truly,

DONALD J. ERICKSON, M.D., *President.*

RESOLUTION

Be it resolved, That the American Congress of Physical Medicine and Rehabilitation be on record as supporting the enactment of an amendment to the Federal Food, Drug and Cosmetic Act, as it pertains to medical devices, by making such devices subject to the provisions of a new device law; be it further

Resolved, That the American Congress of Physical Medicine and Rehabilitation recommended to the U.S. Congress the provision that the Food and Drug Administration be empowered to accept and adopt various physical standards which have been devised, accepted, and recognized as reflecting the expert quali-

fied opinion of representatives of such organizations as are generally accepted and recognized as reflecting the opinion of their respective specialities; be it further

Resolved, That the American Congress of Physical Medicine and Rehabilitation go on record as considering that the advertising of useless devices as acceptable for "adjunctive therapy" has been detrimental to the welfare of the patient. The sense of this resolution is, therefore, in the best interests of the American public, the present laws or regulations being inadequate for the protection of the public from such abuses.

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Washington, D.C., June 18, 1962.

Re statement of views of National Agricultural Chemicals Association on H.R. 11581 and H.R. 11582.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The above bills, on which hearings have been scheduled to begin June 19, 1962, have been carefully studied by National Agricultural Chemicals Association. Agricultural chemicals manufacturers and formulators are not directly covered by this legislation. However, it has been decided to file this statement due to the fact that in many cases a procedure once established by the Food and Drug Administration is extended to other segments of industry.

We have no objection to H.R. 11582.

H.R. 11581, however, contains two provisions against which we, as an industry potentially subject to similar legislation, must strenuously object.

FACTORY INSPECTION PROVISIONS

Title II of H.R. 11581 would broaden the factory inspection authority of the Food and Drug Administration to empower FDA officials to inspect as a routine matter all books, records, files, papers, processes, controls, and facilities of companies and consulting laboratories subject to the act.

The power of government officials to examine private citizens' books and records is an extraordinary police power which normally may be exercised only upon the obtaining of a warrant or a subpena and under circumstances which indicate probability that a crime has been or is about to be committed. On the other hand, the factory inspection provisions of the Federal Food, Drug and Cosmetic Act are intended to enable the Food and Drug Administration to exercise routine and continual surveillance over the factory conditions under which foods, drugs, and cosmetics are manufactured or processed. We do not believe power to examine books and records as a routine matter has been demonstrated to be reasonably necessary to the adequate enforcement of the act.

Power to inspect company books and records as a routine matter would add little, if anything, to the effective enforcement of the adulteration and misbranding provisions of the act. However, by providing easy access to business records and trade secrets of regulated companies without any necessity of a showing of probable cause and without giving private enterprises any means of safeguarding their rights of privacy and of property in trade and business secrets, this legislation would open the door to all sorts of conniving, discrimination, and other abuses.

Accordingly, we believe Congress should not grant to the Food and Drug Administration power to inspect books and records as a routine part of its factory inspection authority. Such extraordinary power is now necessary or appropriate to the effective enforcement of the act and would constitute an unreasonable extension of the Government's police power.

Moreover, we do not believe the attempt, in section 202 of H.R. 11581, to relax the provisions of the act which safeguard the confidentiality of information obtained by FDA officials during the course of their inspections of factories, is justifiable. This attempted relaxation of confidentiality safeguards is especially onerous in view of the above-discussed proposal to broaden the factory inspection authority. We recommend that section 202 of H.R. 11581 be deleted from the bill.

STANDARDIZATION OF DRUG NAMES

We also wish to call to your attention the very serious situations which can result from the establishment of standard names for drug products as provided in title I, part B, of H.R. 11581. If such a provision were extended to our agricultural chemicals industry, it would seriously affect research and marketing.

This industry has had considerable experience in the use of common names since the passage of the Miller pesticide amendment to the Food, Drug, and Cosmetic Act. The problems involved in the arbitrary selection and establishment of common names are serious ones and have a direct effect on trademark registration and the obtaining of patents. The problem is also considerably involved at the present time with the adoption of common names in various European countries, many of which are pirating American trademarks.

Our industry now has a committee studying this entire problem, and for that reason we believe legislation on common names should be given very careful consideration and no immediate action taken at this time.

It is the position of our industry that manufacturers who spend several million dollars in research to develop a product which they expect to place on the market have a property right in such an investment and in the product, and should be able to choose whether a common name should be adopted and if so what the common name should be, or the privilege of merchandising their product under the technical name of a chemical without the use of a common name.

Many of our companies are adopting common names under a procedure now established through the American Standards Association, which is a nonindustry agency equipped to review such proposals. Giving authority to a Government agency to assign a common name to a manufacturer's product without his consent, we believe, is not in the interest of the public, will result in further confusion in world markets, and definitely infringes on the property rights of a developer.

We would appreciate it very much if you would give these comments your careful consideration and make this statement a part of the record.

Very truly yours,

L. S. HITCHNER, *President.*

UNIVERSITY OF OREGON MEDICAL SCHOOL,
Portland, Oreg., August 29, 1962.

HON. OREN HARRIS,
Chairman, Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR SIR: This is in support of the night letter sent to you Wednesday, August 29, a copy of which is enclosed. I have been informed that an objectionable proposal has been written into the bill on drug regulation to be considered on Thursday, August 30, and which bill is similar to S. 1552. This proposal would require those doctors who are looked upon as expert clinical investigators of drugs and who perform trials of new drugs on humans, of which I consider myself one of the group, will be required by law to register with the Secretary of Health, Education, and Welfare each and every time they undertake to test a new drug on patients.

In addition, this proposal requires that at the beck and call of the Secretary, all records, reports, case histories, and other information pertaining to the particular drug under trial shall be submitted to the Secretary. This proposal would limit the interests and activities, as well as be a considerable burden and, as well, be of little value to the Government if included in the new proposed FDA regulations.

The redtape involved in the way of preparation, duplication, secretarial work, and other labor and expenditure of time on the part of the investigator would discourage his interest in conducting such studies. Also, this proposal would be an invasion of the doctor-patient relationship; and would be the submission of privileged communications to a third party (member of the FDA staff) who may not be a physician or qualified "expert" or a pharmacologist knowledgeable in this field.

The proposed amendment as it now reads in the published regulations provided by George Larrick on August 9, and printed in the Federal Register, August 10, 1962, provides that communications from investigators and sponsoring pharmaceutical companies and, from them, be sent to the FDA authorities. Also, the regulations call for the investigator "making available to FDA inspectors all data on research studies." While this last provision may be objectionable to some, I look upon it as satisfactory providing the sponsoring company is informed immediately of such inspections and can cooperate with the investigator and the FDA to reveal and make available any or all information concerning a toxic or adverse effect of the drug.

I am enclosing some material which the Upjohn Pharmaceutical Co. has recently sent me and which I have answered according to the attached photostats.

Very truly yours,

NORMAN A. DAVID, M.D.,
Professor of Pharmacology.

[Night letter]

AUGUST 28, 1962

Representative OREN HARRIS,
Chairman, Interstate and Foreign Trade Committee, Washington, D.C.:

Object to proposal in bill to be considered Thursday that "such regulations may also include provisions requiring said expert clinical drug investigator to register with Secretary HEW, and upon request of Secretary at other times to submit any or all records pertaining to drug investigations undertaken by expert." Such procedures should be through the sponsoring drug company. This proposal, not clearly published in 21 CFR 130 issued August 9, would stifle clinical investigation new drugs as qualified experts would consider this as more Harrison Narcotic Act redtape and an added administrative and secretarial chore. I approve of most of the other provisions of S. 1552, however. Letter follows.

NORMAN A. DAVID, M.D.,
Professor of Pharmacology, University of Oregon Medical School.

[From American Men of Science, 10th ed., 1960, Cattell Press]

David, Dr Norman A(ustin), University of Oregon Medical School, Portland 1, Oregon. Pharmacology. San Francisco, Calif, Oct. 22, 02; m. 32; c. 2. A.B, California, 25, Eli Lilly fellow, 30–32, M.D, 31. Asst. California, 30–32, asst. prof. and head dept. Pharmacol, sch. med, West Virginia, 32–35; asst. prof, col. med, Cincinnati, 35–36, assoc. prof, 36–37; prof and head dept, med. sch, Oregon, 37–; Director, Public Health Venereal Clinic, City Health Dept, Portland, 46–54; Physician, outpatient dept, North. Permanente Hosp, Vancouver, Wash, 44–45. Summers, surgeon Civilian Conservation Camps, U.S. Army, 33–37. With Office Sci. Research & Develop, 42–45; Soc. Pharmacol; Am. Med. Assn; Pres., West. Soc. Clin Research, 1950; Toxicologist, Multnomah County Coroner's Office, 50–; Chairman, Committee Drugs and Pharmacy, Oreg. St. Med. Soc., 1956–; Consultant, Oreg. St. Poison Control Center, 57–; Pres., Multnomah County Med. Soc., 61–62; Pres., West. Soc Pharmacology, 1962; Secty, N.W. Acad. Occupat. Med. Chemotherapy of amebiasis; pharmacology of barbital drugs; chronic effects of opium drugs and synthetic analgesics. Member, Council on Drugs, American Med. Assoc., 1962–.

THE UPJOHN CO.,
Kalamazoo, Mich., August 17, 1962.

NORMAN A. DAVID,
Professor, Head, Department of Pharmacology,
University of Oregon Medical School, Portland, Oreg.

DEAR DR. DAVID: As you are undoubtedly aware, the Federal Food and Drug Administration has published a proposed new regulation controlling the clinical investigation of new drugs (in the Federal Register, Aug. 10, 1962). We feel that you, as an individual who has been interested in clinical drug evaluations, should have the opportunity of reviewing the proposed new regulations and are enclosing a copy for your study.

We of the medical group at the Upjohn Co. feel that the proposed regulations are of profound importance and are most anxious that all parties who will be concerned with their function give careful consideration to the proposal during the 60-day period allowed by the Food and Drug Administration for review. After you have had an opportunity to review the enclosed proposed regulations, we would very much appreciate your honest opinions either in the form of a letter or by completing a short questionnaire which we have included for your convenience. As time is short, we would ask that you return your opinions and comments to us by September 1 at the latest. We will compile the returns from all clinical investigators and make this information available to you and the Food and Drug Administration as soon after September 1 as is possible.

The proposed new regulations contain six amendments to section 130.3. The regulations affecting clinical research investigators in particular are included in paragraph (a), subparagraphs 8 and 9 (pp. 2–3), and subparagraph 12 (pp. 5–7).

Briefly, in the future investigators will be required to —

(1) Submit detailed information supoprting experience and training for research studies.
(2) Submit a detailed protocol to be followed and presumably amendments in advance to cover changes from original.
(3) Report in some detail results of clinical studies.
(4) Report immediately serious side effects or toxicity.
(5) To keep records of drug disposition and accurate case histories.
(6) Make available to FDA inspectors all data on research studies.
(7) Comply with regulations or the FDA is impowered to notify pharmaceutical manufacturers that experimental drugs may not be supplied without special approval of the Commissioner.

We sincerely hope that you will share our regard for the importance of this proposal and make your opinions known to us by September 1, 1962.

Sincerely yours,

HAROLD L. UPJOHN, M.D.

DEAR DOCTOR: After you have had an opportunity to review the Food and Drug Administration's notice of proposal to amend regulations of new drugs for investigational use, we would appreciate your thoughts and opinions, either in the form of a letter or by using this short questionnaire.

As time for review of this proposal is limited, we would urge that you return your comments to us by September 1, 1962. An addressed, stamped envelope is enclosed for your convenience.

Sincerely yours,

THE UPJOHN CO.

	Yes	No	No opinion
In your opinion will the proposed new FDA regulations enable you to perform clinical investigations of new drugs with greater safety to your patients?	☐	☒	☐
Will the regulation stimulate better controlled and designed clinical studies?	☒	☐	☐
Will the proposed "plan of investigation" which investigators will be required to submit in advance of a study seriously restrict your research studies? (see p. 6 of proposed regulations)	☐	☒	☐
Would you agree that pharmaceutical companies and the FDA can and should judge investigator's qualifications for drug research studies? (see pp. 2 and 3)	☒	☐	☐
Do you agree with the proposal that once an investigator has failed to comply with the regulations, he is no longer entitled to receive investigational drugs unless approved by the Commissioner? (see pp. 7 and 8)	☒	☐	☐
Do you agree in principle with making your files and case reports available for inspection by FDA inspectors?	☒	☐	☐
Do you generally approve of the proposed new regulations?	☒	☐	☐

When the proposed regulations become effective, will you modify your study of investigational drugs?

- Stop altogether ☐
- Curtail present number ☐
- No change ☒
- Increase testing ☐

Do you have any suggestions for revisions of the proposed regulations?

Name

Date

Institution or private practice

Percent of time devoted to clinical drug evaluation:

- Less than 5 percent ☐
- 5 to 20 percent ☒
- 20 to 50 percent ☐
- 50 to 100 percent ☐

[Supplement to PMA Newsletter, vol. 4, No. 33, Aug. 9, 1962]

FDA Issues Proposed Regulations Governing Clinical Trials

FDA Commissioner George Larrick today (Aug. 9) issued proposed new regulations governing the testing of drugs in clinical trials. They are reproduced in full in the following pages. Industry has 60 days in which to comment, and final regulations will not be issued until such comments have been considered by HEW and the Food and Drug Administration. In announcing the proposals, HEW Secretary Celebrezze emphasized three points:

(1) The regulations require that FDA be notified and given complete details on distribution of drugs for investigational use.

(2) Manufactures required to satisfy FDA that the investigations will be based on preclinical (chemical and animal) studies of such a nature to assure safety for patients.

(3) The clinical studies would have to be properly planned, executed by qualified investigators and FDA kept fully informed of the progress of the investigations.

The secretary said the "clear purpose" in drawing up the regulations is to impose "no unneeded restrictions on the conduct of investigational research," yet provide assurance that the public will be fully protected against risks that may attend the development of new drugs.

Prior to issuance of these proposed regulations, the Pharmaceutical Manufacturers Association board had scheduled a special meeting for Tuesday, August 14, at PMA headquarters in Washington, D.C., to consider current legislative developments. At that time the board also will study the proposed clinical trial regulations made public today.

In the legislative area, the Senate Judiciary Committee continues its reconsideration of the Kefauver drug control bill, S. 1552, and has agreed to incorporate in it a number of the amendments proposed by President Kennedy. A vote on the Senate floor is likely next week. On the House side, Chairman Oren Harris, of the Interstate and Foreign Commerce Committee, has announced reopening of hearings August 20 on H.R. 11581, the administration's drug control bill. He said hearings will be completed by August 24. During this period PMA witnesses will testify. All of these developments will be reported in detail in the PMA newsletter to be published August 10.

SAN LEANDRO, CALIF., *June 7, 1962.*

Mr. ARTHUR J. YOUNGER,
Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR SIR: I have been a cosmetologist for 25 years, and from experience know that proposed H.R. 11582 will produce definitely measurable adverse effects. I therefore urge you to consider the following:

(1) Many heads of hair become dull and unattractive with age, by reason of chemical changes within the body.

(2) Many positions require certain standards of appearance which would be impossible to achieve without bleaching and coloring of hair.

(3) The national trend toward restricting upper age limits because of retirement benefit costs forces many women to avail themselves of every means of preserving the appearance of youth.

(4) It has been firmly established that morale, among women especially, is directly related to appearance and in these turbulent times attention should be directed to improving our Nation's strength rather than to creating a demoralizing influence.

(5) Part of the most effective argument is eloquently apparent in the fact that bleaching, tinting, and dying constitutes anywhere from 60 to 100 percent of the average salon's volume. Which leads to:

(6) The very livelihood of thousands of people would be directly affected. (There are over 8,000 registered cosmetologists in the State of California alone.) In turn this—

(7) Reduces national income, from which—

(8) Government revenues vary in direct proportion.

Therefore, as president of a local unit, fifth vice president of the California Cosmetologist Association, and a member of the California Hair Fashion Committee, I request that you oppose this bill with vigor and purpose.

Respectfully,

IRIS M. SIMMEAU.

THE PHYSICIANS FORUM, INC.,
New York, N.Y., September 6, 1962.

Congressman OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The Physicians Forum, a national organization of physicians, is delighted that your committee is giving serious consideration to a bill to strengthen Federal control of the prescription drug industry.

The Physicians Forum testified in support of and fully endorsed S. 1552. The purpose of this bill was to promote fair prices and competition as well as to control generic names and descriptive information and assure quality and efficacy of prescription drugs. We still believe that Federal legislation, with all of these provisions, is necessary in addition to voluntary action by industry to correct abuses in the pricing and promotion of drugs as well as to eliminate weaknesses in the current Government regulation of the drug industry.

Enclosed is a statement of the board of directors of the Physicians Forum which fully states our position and which we would like to see included in the record.

Sincerely yours,

LEO MAYER, M.D., *Chairman.*

COSTS, QUALITY, AND PROMOTION OF ETHICAL DRUGS, A STATEMENT OF THE BOARD OF DIRECTORS OF THE PHYSICIANS FORUM, JUNE 1961

Expenditures for ethical prescription and proprietary (over the counter) drugs have increased from $300 million in 1929 to over $2½ billion in 1960. Of this total, close to $2 billion goes for ethical drugs. The average price of a prescription has increased from 90 cents in 1929 to $3.50 in 1960. The greatest part of ethical drug expenditure is attributed to the sale of the wonder drugs and price increase is likewise due to a switch from the low cost and standard pharmaceuticals to the new and more expensive trade-name drugs—to the antibiotics, tranquilizers, antidepression drugs, hormones, metabolic agents, antiobesity drugs, diuretics, anticoagulants, and others. Not only has there been an increase in the average price per prescription, but there has also been an increase in the number of ethical drugs prescribed, from 7.6 per family in 1950 to about 12 per family in 1959, a rise of some 55 percent in 10 years.

Despite this increasing expenditure for new and expensive drugs, the part of the medical-care dollar devoted to drug costs has not shown any increase. In other words, the drug share of the medical dollar, amounting to about 22 cents, has remained about the same in the past 30 years or so.

Drug costs vary a great deal according to age. In 1959, the Senate Subcommittee on Problems of the Aged and Aging showed that while all age groups spend on the average $19 per person per year on drugs, those 65 and over, spend about $42 per person, or about 2½ times as much. The prescription bill of a sick person is usually much higher, often as high as $200 for a chronic illness. In other words, the greatest burden of drug costs is borne by the older age groups, by the population with the most chronic illness and with the greatest need for drugs, and with the least ability to pay for them. While the cost of each prescription has increased in general, the income to pay for them has not.

Another factor contributing to the burden of drug costs is that for the most part they are not covered by medical care insurance.

Confronted with limited income or financial reverses, the average family can and does put off buying automobiles, household appliances, clothes, and even higher priced foods, but they cannot put off buying drugs or find cheap substitutes. Ethical drugs, as Senator Kefauver has expressed it, have an intermediary between the producer and the buyer—the physician who writes the prescription. "In this respect, the drug industry is unusual in that he who buys does not order, and he who orders does not buy." The consumer, in other words, is completely captive. When he is sick, he must buy the drug the doctor orders, and unlike automobile buying, he cannot or does not know how to shop around for a different model or a lower price.

Thus, the pricing policies of the largest pharmaceutical companies are almost completely removed from the corrective discipline of consumer sovereignty, and from the laws of supply and demand. In most instances, drug prices are set by administrative decision and are held constant over extended periods of time. The drug industry is, indeed, a highly competitive industry, but its competitive efforts seem expended mainly in capturing the prescription pads of the busy doctor who in most instances cannot judiciously weigh the real properties of drugs against the promotional claims for it. Competition in prices of drugs has been replaced largely by competition in promotion. Price competition tends to lower prices and increase efficiency. Promotional competition does the opposite—it increases both the use and the price of drugs.

Some critics have contended that the retail druggist's margin is excessive. But this is denied by spokesmen for the retail druggists who point to the high manufacturer's prices of drugs, and the inventory cost of stocking a single drug under a variety of trade names.

When a company has a patent monopoly on a drug or when it licenses one or more companies to package and sell the drug, an understanding is usually reached about the price of the drug, so that the primary company's interests are protected. In such circumstances, the price under the generic name, and the price under the trade name are the same.

Most doctors prescribe by trade name rather than by generic name, and they prefer to do this because trade names are forcefully brought to their attention by effective and sustained promotional methods, and because most trade names are easier to remember and write than the complex industry provided generic equivalents. Another important reason for the preference for trade names is fear that generic products of the smaller companies are not of as high a quality as the trade-name products of the big companies.

That the profits of the drug industry are high is indicated by the following statement in May 1960 issue of Fortune magazine: "There is no doubt that the drug business has been remarkably profitable by all the usual standards. Drug companies commonly earn 15 to 20 percent on invested capital after taxes, and their aftertax margins on sales run 10 to 15 percent, figures that few other manufacturing companies attain except in boom years. The drug company's advantage lies principally in the fact they deal in innovations which in any industry tends to be very profitable." According to the Kefauver committee, the drug industry has a rate of return of 21.4 percent, which is the highest of any manufacturing industry and approximately double that of the average of all manufacturing, which is 11 percent.

Research expenditures to develop new products have been cited by manufacturers as an important factor contributing to current drug prices. However, expenditure for research by the 20 largest drug companies is only 6.4 percent of sales. Much of this research has been termed "molecule manipulation," "me-too" research.

Selling expenditures, including promotion by detail men, brochures, pamphlets, newspapers, magazines, special conferences, cocktail parties, golf tournaments, phonograph records, and other methods account for 24 cents of the sales dollar or almost four times the amount spent on research.

The Physicians Forum fully endorses Senate bill S. 1552 introduced by Senator Estes Kefauver.

In general the legislation is designed to promote competition and protect the public interest in these principal ways:

1. By making it unlawful under the antitrust laws for large drug companies to agree upon which company will obtain a patent, to agree which companies shall be awarded licenses in the event that a patent is issued, and to make similar restrictive agreements.
2. By requiring compulsory licensing of qualified applicants (after 3 years) under the product patents for prescription drugs.
3. By providing that the Food and Drug Administration shall pass on the efficacy as well as the safety of drugs.
4. By seeing to it that physicians are provided with clearer, better, and additional information on the bad as well as the good features of drugs.
5. By requiring fuller and more comprehensive inspection of drug manufacturing plants, thereby giving to physicians greater confidence in prescribing on the basis of generic rather than trade names.
6. By providing for the licensing of drug manufacturing companies which should also give physicians greater confidence in prescribing by generic names since a company could lose its license to do business if it did not meet the requirements of the Food and Drug Administration.
7. By giving to the Food and Drug Administration authority to establish the official or generic names for drugs, thereby providing a means of simplifying generic names which, in contrast to the short and simple trade names, are often so long, complex and unpronounceable that they are not remembered or used by physicians.

Much is wrong with prices and promotion of ethical drugs: obviously Federal legislation is necessary in addition to voluntary action by industry to correct abuses and regain deficiencies in Government regulation of the drug industry.

Mr. ROBERTS. The hearings are now adjourned.

(Whereupon, at 12:30 p.m., the hearing was adjourned.)

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